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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as *guardians ad litem* of the infant ROSIE GROSSBAUM,

Plaintiffs,

-vs-

GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITALS CENTER, both corporations in the State of New York, ABC CORPS. 1-10, JOHN DOES 1-10,

Defendants.

CIVIL ACTION NO.
07-CV-1359 (GEB)(ES)

GENESIS'S REPLY RULE 56.1 STATEMENT OF UNDISPUTED FACTS (INCORPORATING PLAINTIFFS' AND NYU'S RESPONSES TO GENESIS'S JANUARY 20, 2011 RULE 56.1 STATEMENT) AND GENESIS'S RESPONSES TO PLAINTIFFS' FEBRUARY 17, 2011 SUPPLEMENTAL RULE 56.1 STATEMENT

Pursuant to Local Civil Rule 56.1, Defendants Genesis Genetics Institute ("Genesis Genetics") and Mark R. Hughes ("Hughes") (collectively, "Genesis") respectfully submit the following Statement of Undisputed Material Facts Pursuant to Local Civil Rule 56.1 in further support of their motion for summary judgment. This version of the Rule 56.1 statement incorporates the following documents as well as Genesis's responses thereto: (1) Genesis's January 20, 2011 Rule 56.1 Statement; (2) Plaintiffs' February 17, 2011 Responses to Genesis's January 20, 2011 Rule 56.1 Statement; (3) NYU's February 17, 2011 Responses to Genesis's January 20, 2011 Rule 56.1 Statement; and (4) Plaintiffs' February 17, 2011 Supplemental Rule 56.1 Statement of Undisputed Material Facts. Because NYU did not move for summary judgment against Genesis, Genesis is not required to submit a Rule 56.1 Response to NYU's January 20, 2011 Rule 56.1 Statement of Undisputed Material Facts.

The following are material facts as to which Genesis contends that there are no genuine issues to be tried:

I. PLAINTIFFS' INTERACTIONS WITH GENESIS AND NYU

1. As high school students, Plaintiffs Chaya and Menachem Grossbaum, who both attended Jewish day schools, were tested by a community organization, Dor Yeshorim, to see if they were carriers of a number of genetic mutations that are more prevalent than average within the Jewish community. (Ex. 9[1] (Deposition of C. Grossbaum, Vol. I, 12/17/08) at 39:18 - 43:8.) When Chaya and Menachem Grossbaum were considering getting engaged, they contacted the organization that conducted the screening to see whether they were "compatible or not." (Id. at

[1] Citations to Ex. __ are citations to the exhibits to the Declaration Of Sarah Blaine, Esq. In Support Of Genesis Genetics Institute, LLC And Mark R. Hughes's Motions for Summary Judgment And To Disqualify Plaintiffs' Liability Experts, submitted simultaneously with Genesis's moving papers. Citations to Blaine Supp. Decl. Ex. ___ are to the Supplemental Declaration Of Sarah Blaine, Esq., submitted simultaneously with Genesis's reply papers.

40:15.) At that time, they learned that they were both carriers of cystic fibrosis ("CF"). (Id. at 40:15 - 17.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted that, when plaintiffs Chaya and Menachem Grossbaum ("plaintiffs") were considering becoming engaged, they were informed by Dor Yeshorim in 2000 that previously performed genetic tests conducted by that organization indicated that both Chaya and Menachem were CF carriers. The remainder of paragraph 1 is rejected as not supported by the cited testimony, and as immaterial.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further reply needed.

2. When both parents are carriers of CF mutations, there is a 25% chance that any child they conceive together will have CF. (Ex. 8 (Deposition of Menachem Grossbaum, 3/12/09) at 18:15 - 25.)

NYU RESPONSE: Accepted, but subject to the understanding that the percentage relates to natural conception without PGD.

PLAINTIFFS' RESPONSE: Contains a statement of scientific fact which is not disputed except to the extent that the deposition of the Plaintiff as source of the fact is patently hearsay.

GENESIS'S REPLY: No further reply needed.

3. Upon learning of their carrier status, the Grossbaums consulted a number of rabbis for advice on (1) whether to get married, and, if they did choose to get married, (2) what reproductive options were available to them under Jewish law. (Ex. 9 at 45:12 - 50:23, 64:10 - 66:12, 179:18 - 180:4; Ex. 8 at 12:1 - 15:1.)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed except for the description that "the Grossbaums consulted a number of rabbis for advice." In fact, decided references disclose that the parties consulted two rabbis with respect to the subject matter stated. One was a close acquaintance of Chaya Grossbaum and a doctor, Rabbi Markowitz; and the second was Rabbi Tendler who was considered an authority on the subject.

GENESIS'S REPLY: No further reply needed.

4. Because of their religious convictions, Chaya and Menachem Grossbaum are both opposed to abortion, and their deposition testimony reflects that, in accordance with their understanding of Jewish law, they would not opt to abort if they learned that Chaya Grossbaum was carrying a child with CF. (Ex. 9 at 66:5 - 12; Ex. 8 at 18:5 - 14.) They reached this conclusion based on advice they received from Rabbi Tendler, a leading authority in applying Jewish religious law to reproductive issues. (Ex. 8 at 15:2 - 16:21.)

NYU RESPONSE: Accepted, except for the description of Rabbi Tendler as "a leading authority," which is not provided by the cited testimony, and subject to the understanding that, according to the cited testimony, the advice may also have come from two other rabbis who attended the same meeting

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further reply needed.

5. Rabbi Tendler confirmed that Jewish law would not condone a decision to abort a fetus that had CF, but suggested that Plaintiffs could get married and then reduce their risk of becoming the parents of a child with CF by undergoing IVF and PGD to build their family. (Ex. 8 at 15:11 - 15; 19:10 - 14.)

NYU RESPONSE: Accepted, but subject to the understanding that, according to the cited testimony, the advice may also have come from two other rabbis who attended the same meeting.

PLAINTIFFS' RESPONSE: Not disputed except that there is no evidence in the cited material that Rabbi Tendler incorporated in his advice the terminology, "reduced their risk."

GENESIS'S REPLY: Menachem Grossbaum's deposition testimony (Ex. 8 at 19:10-14) speaks for itself:

Q. So what was your understanding as to the potential benefit of using IVF and PGD based upon your discussion with Rabbi Tendler?
A. That it would bring down the risk of having a child with CF.

6. The Grossbaums got married on August 22, 2002. (Ex. 9 at 9:17 - 18; Ex. 8 at 8:22 - 9:2.)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further reply needed.

7. From the date of their wedding until after the birth of the infant plaintiff, Rosie Grossbaum, the Grossbaums lived in Brooklyn, New York. (Ex. 9 at 9:22 - 10:14.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted that the cited testimony states that plaintiffs lived in Brooklyn from the time they were married in August of 2002 until sometime in 2005. The remainder of paragraph 7 is rejected, because the cited testimony does not support the statement that plaintiffs lived continuously in Brooklyn from the date of their marriage until after the minor plaintiff's birth, and because the statement and cited testimony do not discuss the plaintiffs' contacts with New Jersey including prenatal care, family interactions, and other matters.

PLAINTIFFS' RESPONSE: Not disputed as stated; however, see Declaration of Chaya Grossbaum at P1. Exh. 3.

GENESIS'S REPLY: Genesis rejects NYU's response as unsupported by the record and Plaintiffs' admissions. (See Pl. Opp. Br. at 3; Feb. 14, 2011 Chaya Grossbaum Decl., Pl. Ex. 3, at ¶ 1.)

8. Because of their status as CF carriers, in late 2003 or early 2004, when the Grossbaums decided they were ready to start a family, they sought out the Program for IVF, Reproductive Surgery and Infertility at New York University School of Medicine (together with co-defendant New York University Hospitals Center, hereinafter "NYU" or the "NYU Defendants"). (Ex. 9 at 192:5 - 194:6; Ex. 8 at 20:11 - 21:13; Ex. 13 (Chaya Morganstern-Grossbaum's NYU Medical Records) at CG046.)

NYU RESPONSE: Rejected as stated. Accepted that the cited testimony of Mr. Grossbaum and the cited letter indicate that plaintiffs went to NYU for the reasons stated, but on the recommendation of one or more rabbis.

PLAINTIFFS' RESPONSE: Not disputed except that the Grossbaums first contact with NYU Fertility Clinic was on February 4, 2004. In addition, the Grossbaums consultation at NYU was the result of the recommendation of Rabbi Jacobowitz and not any independent investigation by the Plaintiffs of locations for obtaining IVF. (See Genesis Exh. 13 at CG003.)

GENESIS'S REPLY: Accepted that the Grossbaums chose NYU on the basis of referrals they received from one or more rabbis, including Rabbi Jacobowitz, who was also a medical doctor and who was affiliated with NYU. See Blaine Decl. Ex. 13, at CG046.

9. NYU is located on First Avenue in New York, New York. (Ex. 17 (NYU Semen Collection Record); Ex. 19 (NYU Consent Agreement).)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further reply needed.

10. Plaintiffs agreed to undergo in vitro fertilization ("IVF") treatment at NYU, and then to have cells from the embryos they created through IVF biopsied and sent to defendant Genesis Genetics Institute, LLC (together with its founder and director, individually named defendant Mark R. Hughes, hereinafter "Genesis") for genetic analysis intended to determine which embryos were affected with CF. (Ex. 9 at 49:4 - 25; Ex. 8 at 21:14 - 16.)

NYU RESPONSE: Accepted, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, plaintiffs first spoke with defendant Hughes in detail about PDG and IVF before they spoke with the NYU defendants' Dr. Licciardi or any of his colleagues; that plaintiffs agreed to proceed with IVF and PGD processes based upon what Hughes said to them about the 2-3% PGD error rate of risk of developing a CF affected child, rather than on the higher risk provided by NYU; and that plaintiffs would not have decided to proceed if the error rate or risk provided by Hughes had been higher than 2-3%.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further response needed as to Plaintiffs. As to NYU's "understandings," Genesis notes that Plaintiffs contacted NYU on February 4, 2004, more than six weeks before they first contacted Genesis. (Ex. 13, at CG003.) NYU's contentions that Plaintiffs "agreed to proceed with IVF and PGD processes [sic] based upon what Hughes said to them about the 2-3% error rate of risk [sic] of developing a CF affected child, rather than on the higher risk provided by NYU; and that plaintiffs would not have decided to proceed if the error rate or risk provided by Hughes had been higher than 2-3%" are unsupported by citations to the record and therefore Genesis's Rule 56.1 Statement is deemed accepted on this point. Regardless, NYU's purported facts are irrelevant to resolving Genesis's summary judgment motion.

11. Genesis Genetics Institute, LLC is a Michigan limited liability corporation with its sole place of business in Detroit, MI. (Ex. 22 (Complaint And Jury Demand) at ¶ 3.) Mark R. Hughes, its founder and director, has been a

Michigan resident since 1998, and has been employed by Genesis Genetics Institute, LLC at its sole place of business in Detroit, Michigan since he founded it in 2003. (Ex. 6 (Declaration Of Mark R. Hughes In Support Of The Genesis Defendants' Motion For Summary Judgment) at ¶¶ 5, 6.) Genesis specializes in testing embryos of couples who are carriers for genetic diseases in an effort to help those couples reduce their risk of having children affected with those diseases. (Ex. 6 at ¶ 6.)

NYU RESPONSE: Accepted, but subject to the understanding that: (1) as established by Genesis/Hughes' Exhibit 7 ("We are not your physicians."), by paragraph 1 of Hughes' declaration (Genesis/Hughes' Exhibit 6) ("I am a genetics research scientist specializing in studying the human genome of DNA and the technology of pre-implantation genetic diagnosis ('PGD')"), and by the excerpts of Hughes' deposition testimony attached to this response as Exhibit A (2/19/09 deposition of Mark Hughes, p. 16-17; 5/14/10 deposition of Mark Hughes, p. 27-29), Genesis/Hughes had no doctor-patient relationship with plaintiffs; Hughes was not practicing medicine in connection with the advice and PDG services that he and Genesis gave to and performed for plaintiffs; at the time Hughes and Genesis advised and performed PDG services for plaintiffs, Hughes did not have an active medical license, did not have hospital privileges, and did not see patients; what he did in advising and performing PDG services was science performed under his Ph.D., not medicine under his lapsed M.D.; and even his informed consent discussion with plaintiffs was "[n]ot even remotely" the practice of medicine, but "[i]t's more like a genetic counselor"; (2) there is no indication in the record of this case that Genesis/Hughes were licensed or regulated as medical providers in connection with their PDG-related activities with respect to plaintiffs or to any other clients in 2004; and (3) there is no indication in the record of this case that Genesis/Hughes limited its PDG-related activities to clients from any particular state or that Genesis/Hughes relied on the law of Michigan or New York in performing its PDG-related activities for plaintiffs or for any other clients in 2004.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further reply needed as to Plaintiffs. NYU's citations to the record speak for themselves. NYU's unsupported contentions, including, inter alia, NYU's legal conclusions regarding

whether Genesis was practicing medicine, relied on the law of any particular state, or was licensed as medical providers are unsupported by the record, not based on any citations to the record as required by Local Civil Rule 56.1, and should be rejected. Nevertheless, as set forth in Genesis's Reply Brief, these factual disputes are irrelevant to resolving Genesis's summary judgment motion in Genesis's favor. Genesis Reply Br. § III.A.

12. The Grossbaums, upon NYU's referral, called Genesis's Michigan laboratory on March 25, 2004 for an approximately one-hour phone conversation with Hughes to review the PGD procedure as part of the informed consent process. (Ex. 8 at 21:14 - 16; Ex. 7 (Pre-Case Phone Review of PGD Informed Consent); Ex. 13 at CG037 (Mar. 22, 2004 email from M. Hughes to NYU stating that "we need [the Grossbaums] to call for their phone consultation" with handwritten note indicating dialing information and the Grossbaums' appointment time for their telephone consultation with Mark Hughes); Ex. 13 at CG004 (Mar. 25, 2004 email from M. Hughes to F. Hooper at NYU stating that "I have spoken with the [Grossbaums] at length"); Ex. 13 at CG046 (April 29, 2004 letter from NYU's F. Liccardi to Rabbi Jacobwitz stating that the Grossbaums "have already contacted Mark Hughes to set up biopsy testing").)

NYU RESPONSE: Accepted, but subject to the understanding that: (1) plaintiff's approximately one hour consultation with Hughes occurred before their consultation with Dr. Licciardi (see Genesis/Hughes Exhibit 13 at CG004 (3/25/04 email from Hughes to Hooper at NYU stating in pertinent part, "Chaya Morgenstern and Mendel Grossbaum will be coming in next week, Tuesday I think, for an initial visit with Fred Licciardi. I have spoke with the couple at length. They can start IVF whenever it is convenient for them and NYU."); and (2) as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, plaintiffs first spoke with defendant Hughes in detail about PDG and IVF before they spoke with the NYU defendants' Dr. Licciardi or any of his colleagues; that plaintiffs agreed to proceed with IVF and PGD processes based upon what Hughes said to them about the 2-3% PGD error rate of risk of developing a CF-affected child, rather than on the higher risk provided by NYU; and that plaintiffs would not have decided to proceed if the error rate or risk provided by Hughes had been higher than 2-3%.

PLAINTIFFS' RESPONSE: Not disputed except that the characterization of the communication being "part of the informed consent process" is a conclusion that is more expansive than is supported by the facts asserted. Plaintiff does note that the Defendant's record of the conversation bears the label, "informed consent"; but to characterize it as a process is purely conclusionary by these Defendants.

GENESIS'S REPLY: No further response needed as to Plaintiffs. As to NYU's "understandings," Genesis notes that Plaintiffs contacted NYU on February 4, 2004, more than six weeks before they first contacted Genesis. (Ex. 13, at CG003.) NYU's contentions that Plaintiffs "agreed to proceed with IVF and PGD processes [sic] based upon what Hughes said to them about the 2-3% error rate of risk [sic] of developing a CF affected child, rather than on the higher risk provided by NYU; and that plaintiffs would not have decided to proceed if the error rate or risk provided by Hughes had been higher than 2-3%" is unsupported by the record, contains no citations to the record, does not comply with Local Civil Rule 56.1, and should be rejected by this Court as unsubstantiated. Regardless, NYU's purported facts are irrelevant to resolving Genesis's summary judgment motion.

13. Following the March 25, 2004 discussion, the Grossbaums executed Genesis's informed consent document, which was sent to Genesis for its files. (Ex. 13 at CG093 - CG097 (Preimplantation Genetic Diagnosis Patient Informed Consent).)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed except that the statement is incomplete since the informed consent document bears the date of June 4, 2004, more than two months after the discussion of March 25, 2004.

GENESIS'S REPLY: No further reply needed.

14. Pursuant to NYU's instructions, the Grossbaums sent their payment for the PGD testing directly to Genesis at its Michigan facility. (Ex. 28 (Genesis Genetics Institute Paid Invoice); Ex. 29 (May 22, 2004 through January 25, 2005

email chain including Chaya Grossbaum, Genesis's Shannon Wiltse, and NYU's Francis Hooper).)

NYU RESPONSE: Accepted in part and rejected in part. Rejected that plaintiffs sent their payment to Genesis at NYU's instructions, because the cited Exhibit 29 establishes that Genesis' Sharon Wiltse provided those instructions directly to Mrs. Grossbaum; the remainder of paragraph 14 is accepted.

PLAINTIFFS' RESPONSE: Not disputed except that the documentation provided in support (Genesis Exh. 28) does not address any instructions from NYU.

GENESIS'S REPLY: No further reply needed.

15. In late June and July of 2004, the Grossbaums underwent IVF with NYU, and PGD with Genesis. (Ex. 13.)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further reply needed.

16. Chaya Grossbaum took the fertility medications required as part of the IVF process, which increased the number of mature eggs her body produced that month. (Ex. 13 at CG010 (noting that 33 oocytes were retrieved); Ex. 13 at CG059 (Oocyte Retrieval Operative Report); Ex. 13 at CG069 (recording use of fertility medication Follistim).)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further reply needed.

17. Despite Chaya Grossbaum's significantly increased fertility, the Grossbaums chose not to abstain from intercourse during the fertility treatment cycle, even though abstaining, of course, was the only 100% reliable method of assuring that any ensuing pregnancy would develop from an embryo tested by Genesis. (Ex. 13 at CG129 (IVF Semen Collection Record); Ex. 9 at 148:21 - 151:18; Ex.8 at 57:17 - 58:12.)

NYU RESPONSE: Accepted, but subject to the understanding that it is for the fact-finder to determine the credibility of the plaintiffs' testimony.

PLAINTIFFS' RESPONSE: Disputed since: (a) use of the terminology, "Grossbaums chose not to abstain from intercourse", suggests the Grossbaums disregarded medical advice as to when to abstain from intercourse; (b) failed to define what aspect of the fertility treatment cycle this paragraph refers to; and (c) offers an opinion that abstaining was the only reliable method on assuring the ensuing pregnancy would develop from the embryo tested by Genesis Genetics. The documentation for the allegations of this paragraph does not support the conclusions suggested by the opinion statement within the paragraph. Semen collection record distinguishes between intercourse and ejaculation. In addition, the testimony of the Plaintiff at depositions indicates that she followed explicitly the directions of the IVF Dept. at NYU and in no way did she disregard their instructions.

GENESIS'S REPLY: Plaintiffs fail to cite to any record evidence in support of their statements that these facts are disputed. Further, Genesis does not contend that Plaintiffs disregarded medical advice as to when to abstain from intercourse. This paragraph refers to Plaintiffs' failure to abstain from intercourse during the IVF cycle, and, specifically, the portion of the cycle in which Chaya Grossbaum's ovaries were stimulated to produce multiple mature eggs instead of the single mature egg normally produced by a woman's ovaries each month. The IVF Semen Collection Record and referenced testimony establishes that Plaintiffs had intercourse two days prior to the egg retrieval as well as the morning of the egg retrieval. (Ex. 13 at CG129 (IVF Semen Collection Record); Ex. 9 at 148:21 - 151:18; Ex.8 at 57:17 - 58:12.)

18. Instead, during their IVF cycle the Grossbaums used an over-the-counter spermicide without a second form of protection, such as a condom, in an attempt to prevent a non-IVF pregnancy. (Ex. 9 at 187:24 - 188:12.)

NYU RESPONSE: Accepted, but subject to the understanding that it is for the fact-finder to determine the credibility of the plaintiffs' testimony.

PLAINTIFFS' RESPONSE: Disputed. This statement of fact is vague in that it does not define with specificity what is meant by "during their IVF cycle." In addition, the state of mind of the Plaintiffs characterized as "an attempt to prevent a non-IVF pregnancy" is a conclusion not supported by the record. It is clear from the testimony of the Plaintiff, and there is no indication in the records referred to, that the Plaintiffs abstained from intercourse, including the use of protection, spermicide or condom, when they were instructed to abstain.

GENESIS'S REPLY: Genesis does not dispute that Plaintiffs abstained whenever they were instructed by NYU to abstain from intercourse. Rather, Genesis notes that the record establishes that Plaintiffs did not abstain from intercourse two days prior to Chaya Grossbaum's egg retrieval as well as on the morning of the egg retrieval. (Ex. 13 at CG129.) To the extent that Plaintiffs' response alleges that Plaintiffs were not trying to prevent a naturally occurring pregnancy by using birth control in July of 2004, Genesis is willing to accept that characterization of Plaintiffs' activities. Regardless, the dispute about the characterization of Plaintiffs' intent is irrelevant to the resolution of Genesis's summary judgment motion vis-à-vis causation, which only requires the fact that Plaintiffs have offered no evidence other than speculation concerning whether Rosie Grossbaum originated from a naturally occurring or Genesis-tested embryo.

19. Spermicide, used alone, of course, is a notoriously ineffective contraception method, even where the woman is not also on fertility medications. (Ex. 26.)

NYU RESPONSE: Rejected, because Exhibit 26 has not previously been introduced during discovery; it has not been properly authenticated or proven reliable; and it does not support the statement for which it is cited.

PLAINTIFFS' RESPONSE: Disputed. This statement is a conclusion drawn apparently from three learned treatises. Those treatises have never been identified in discovery, their content is not relevant to the particular subject at hand, was never the subject of medical opinion and refers to broad population bases and not specifically to the conduct of the Plaintiffs. Also, the literary references are in large measure based on the conduct of individuals, especially in which their educational level is a significant factor. Finally, it should not be misunderstood that one of the literary references refers to the effectiveness of a condom in and of itself when properly used as a 1008 protection against pregnancy. In addition, before the conclusions could be made specific to the use of the Plaintiffs contraception, the Court should require the clinical trial evidence provided to the FDA at the time these products were approved for use which would indicate the effectiveness of the contraception itself unrelated to the educational level and efficiency of the individual using it. Also, in order for these conclusions to be considered, the Court would have to know the extent to which the Plaintiffs used the kind of contraception that was used here over the several years of marriage to determine the effectiveness of the use of contraception.

GENESIS'S REPLY: This Court may take judicial notice of the widely accepted failure rates of popular methods of birth control, including condoms and spermicide. Many organizations publish such statistics, which are commonly taught in high school sexual education courses across the nation. See Blaine Supp. Decl. at Ex. 33 (Planned Parenthood Chart titled "Comparing effectiveness of birth control methods"). The Planned Parenthood Chart indicates that approximately 30 out of 100 women using spermicide as a birth control method will become pregnant each year.

20. The July 12, 2004 intercourse was, according to Chaya Grossbaum's testimony, with spermicide, used alone, and the IVF Semen Collection Record reflects that the July 14, 2004 intercourse was with a condom that did not contain spermicide, as this condom was used to collect the sperm to be used to fertilize Chaya Grossbaum's retrieved eggs. (Ex. 9 at 187:24 - 188:12, 191:1-4; Ex. 13 at CG129 (IVF Semen Collection Record dated July 14, 2004).)

Condoms, especially used without spermicide, have a significant failure rate. (Ex. 26.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted, but subject to the understanding that it is for the fact-finder to determine the credibility of the plaintiffs' testimony. Rejected, because Exhibit 26 has not previously been introduced during discovery; it has not been properly authenticated or proven reliable; and it does not support the statement for which it is cited.

PLAINTIFFS' RESPONSE: Disputed. The statement that "the July 12, 2004 intercourse was, according to Chaya Grossbaum's testimony, with spermicide, used alone" is not supported in any testimony by Chaya Grossbaum provided by this Defendant. In addition, the further reference that "on July 14, 2004, intercourse was with a condom that did not contain a spermicide" suggests that it was in some way appropriate for the condom to contain a spermicide. This is not supported in the record. It is admitted that the condom at that time was used to collect the sperm to be used in the IVF procedure of Chaya Grossbaum's retrieved eggs. Moreover, the statement "condoms, especially used without spermicide, have a significant failure rate" is a conclusion drawn from the citation of certain learned treatises which have not been established as being relevant to the particularized Plaintiffs in this case.

GENESIS'S REPLY: Plaintiffs do not cite to any record testimony in support of their attempt to dispute when and using what birth control methods Plaintiffs had intercourse during the July 2004 IVF cycle. The referenced testimony and documents speak for themselves, and establish that Plaintiffs had intercourse on at least July 12, 2011 (two days prior to the egg retrieval, presumably using spermicide alone) and July 14, 2011 (the morning of the egg retrieval, using a sterile collection condom that did not contain spermicide). It is critical that egg donors or fertile couples seeking PGD to prevent birth defects abstain from intercourse while taking fertility medications to prevent naturally occurring pregnancies. (*See* Blaine Supp. Decl. at Exs. 34, 35.) Although during the egg retrieval procedure, the physician attempts to remove all of the eggs the woman has produced, this process is far from 100% accurate, and, indeed, the risk of multiple pregnancies enhanced by use of fertility medications during the IVF cycle is the primary reason that egg donors are cautioned not to have intercourse during the IVF cycle. *See* Blaine Supp. Decl. at Ex. 34, 35.

These facts are offered merely to establish that Plaintiffs have failed to

provide evidence that Rosie Grossbaum developed from a Genesis-tested rather than naturally occurring embryo. Genesis's outside liability expert, Dr. Kangpu Xu, opined "[w]ith this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums." (Blaine Decl. Ex. 5 at 3.) Indeed, even Plaintiffs' expert, Dr. Charles Strom, testified that he could not rule out that the pregnancy in this case developed from "a non-implanted embryo." (Supp. Blaine Decl. Ex. 31 at 178:17-19.)

This Court may take notice of the efficacy rate for male condoms, which is that 15-25 out of 100 women will become pregnant each year if they are using male condoms as their birth control method. Blaine Supp. Decl. Ex. 33 (Planned Parenthood Chart titled "Comparing effectiveness of birth control methods"). Nothing in Plaintiffs' response indicates that the sterilized collection condom used by Plaintiffs on July 14, 2004 had greater efficacy rates than those ascribed to condoms generally.

21. Later on July 14, 2004, an NYU physician retrieved 33 eggs from Chaya Grossbaum's ovaries as part of the IVF process. (Ex. 13 at CG059.) That same day, ten of Chaya Grossbaum's retrieved eggs were successfully fertilized with Menachem Grossbaum's sperm at NYU's facility. (Ex. 13 at CG133.)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: No further response required.

22. On July 17, 2004, an NYU embryologist, as requested by the Grossbaums, biopsied their embryos and sent one cell from each embryo to Genesis's Michigan laboratory for analysis. Genesis tested the cells at its Michigan laboratory. (Ex. 13 at CG135 - CG136; Ex. 8 at 56:7 - 13.)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed. However, Plaintiffs note that the extent to which the use of the language, "requested by the Grossbaums," is intended to exclude the relationship between Genesis Genetics and NYU, and the extent to which NYU recommended the use of the Genesis Genetics Laboratory.

GENESIS'S REPLY: No further response required. Plaintiffs' commentary regarding Genesis's alleged intent is neither correct nor relevant to the motions before the Court.

23. On July 19, 2004, Genesis faxed to NYU a document addressing the potential transfer of several embryos. (Ex. 13 at CG064, CG125.)[2] In this document, Genesis stated "OK for transfer" as to two (2) of the embryos, designated as nos. 8 and 10. Id. The document also addressed analysis of the cells biopsied from other embryos. Id. The embryos themselves remained physically located at the NYU Fertility Clinic throughout the IVF process. (Ex. 13 at CG131 - CG134.) On July 19, 2004, only NYU personnel, and through them the Grossbaums, had knowledge of the quality of the embryos. (Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, (1) the one-page 7/19/04 evaluation report from Genesis/Hughes indicated that embryo 7 was also genetically suitable for implantation, and (2) although two other communications from Genesis to NYU exist in the Genesis chart for the plaintiffs, a more formal analytical report and a note, there is no evidence of record that either of those communications were sent to, or received by, NYU; to the contrary, the evidence of record demonstrates that neither of those documents were part of the NYU records. Rejected that "only NYU personnel, and though them the Grossbaums, had knowledge of the quality of the embryos," because Genesis/Hughes, as the PGD testers, knew or should have known the actual genetic condition of the embryos.

[2] The parties hotly dispute whether Genesis's full second report was received by NYU. This issue, however, is not relevant to Genesis's Motion For Summary Judgment, which does not include or rely on the disputed second report.

PLAINTIFFS' RESPONSE: Disputed as stated. This Defendant is being sly in the use of the term, "a document," since NYU records infer that this was the one and only report by Genesis Genetics of its analysis of the cells sent by NYU that were extracted from the Grossbaum embryos. The document purported to describe the suitability for implantation of all of the cells from the 10 embryos sent to Genesis by NYU. It is not disputed that the Genesis report stated "okay for transfer" as to 2 of the embryos designated as Nos. 8 and 10. The report also similarly stated the nature of the results of the Genesis studies of the remaining 8 embryos' cells without indicating that the remaining 8 were "okay for transfer." It is not disputed that the embryos themselves remained physically located at NYU Fertility Clinic throughout the IVF process. It is also not disputed that on July 19, 2004 NYU personnel had knowledge of the quality of the embryos. The statement that "the Grossbaums had knowledge of the quality of the embryos" is overly broad and implies a greater degree of knowledge about the embryos than is evident from the record.

GENESIS'S REPLY: The record and parties' credibility speak for themselves concerning whether NYU received the Genesis second report, but that credibility determination is not relevant to the Court's ability to decide Genesis's summary judgment motion in Genesis's favor. Genesis does not dispute that it was aware of the "genetic" condition of the embryos as apparent from its testing of the embryos; rather, it intended to express that only NYU had data concerning the development and progress of each embryo in its laboratory following the Day 3 embryo biopsies. Furthermore, Genesis has no intention of being "sly" or otherwise misleading the Court. Indeed, Genesis's Footnote 2 alerting the Court to the dispute between Genesis and NYU concerning the final report was specifically intended to avoid such characterizations of Genesis's intent. Plaintiffs do not identify any material disputes regarding the facts as set forth by Genesis in this paragraph.

24. The determination as to the suitability of embryos for in vitro fertilization based upon the results from Genesis was made by NYU reproductive endocrinologist Dr. Frederick Licciardi and NYU embryologist Alexis Adler. (Ex. 9 at 154:5 - 156:23; Ex. 13 at CG134.) Without consulting anyone at Genesis, Licciardi and Adler decided to replace embryo no. 10 with embryo no. 7. The

Grossbaums concurred in this decision. (Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.)

NYU RESPONSE: Accepted, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, including the deposition testimony of Hughes, the one-page 7/19/04 evaluation report from Genesis/Hughes indicated that embryo 7 was also genetically suitable for implantation.

PLAINTIFFS' RESPONSE: Not disputed except the statement, "the Grossbaums concurred in this decision," is not supported by the record since there is no evidence that the decision to replace Embryo No. 10 with Embryo No. 7 was the focus of any discussion between Dr. Frederick Licciardi and the Grossbaums.

GENESIS'S REPLY: The cited document speaks for itself. Embryo 7 was characterized as "Carrier at worst" not "genetically suitable for implantation." (Ex. 13, at CG064.) Chaya Grossbaum's participation in the embryo transfer indicates that the Grossbaums concurred in the decision to the extent -- if any -- that they were informed of it by NYU. (Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.) Furthermore, despite the distinctions in Genesis's assessment of the embryos, there is no evidence in the record that NYU's Adler or Liccardi consulted their NYU colleague, Jamie A. Grifo, MD, PhD for expert advice interpreting the PGD results, despite the fact that Grifo's "scientific interests are focused in area of pre-implantation genetic diagnosis and his team had the first successful delivery in the United States from the embryo biopsy procedure." Supp. Blaine Decl. at Ex. 37.

25. That same day, July 19, 2004, embryos no. 7 and 8 were implanted in Chaya Grossbaum. (Ex. 13 at CG134.) Genesis did not learn that NYU had substituted embryo 7 for embryo 10 prior to the embryo transfer. In fact, following its July 19, 2004 report of its results, Genesis had no further involvement with Chaya Grossbaum's IVF cycle or subsequent pregnancy other than making some inquiries to NYU to try to ascertain the cycle's outcome for its records. (Ex. 13; Ex. 9 at 153:12 - 23; 186:19 - 25; Ex. 29.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted that embryos 7 and 8 were implanted in Chaya Grossbaum on July 19, 2004 after receipt of and in reliance on the Genesis/Hughes PGD analytical report, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, including the deposition testimony of Hughes, the report indicated that embryo 7 was also genetically suitable for implantation. The remainder of paragraph 25 is rejected as immaterial.

PLAINTIFFS' RESPONSE: Not disputed except the statement, "making some inquiries to NYU," cannot be documented by the references supplied. Those references indicate a single inquiry by NYU on January 25, 2005 as reflected in Genesis Exh. 29.

GENESIS'S REPLY: Exhibit 12 characterizes embryo 7 as "Carrier at worst" and not as "genetically suitable for implantation." NYU's characterization of its decision to implant embryos 7 and 8 "after receipt of and in reliance on the Genesis/Hughes PGD analytical report," to the extent that NYU interprets that "analytical report" as Exhibit 12, standing alone, is disputed (see Footnote 2 and Genesis's Reply to NYU and Plaintiffs' Responses to ¶ 23), but this dispute is irrelevant to resolving Genesis's summary judgment motion in Genesis's favor. Plaintiffs' contention that NYU made a single inquiry regarding the cycle's outcome is rejected, but irrelevant to the analysis.

26. Genesis has always required that a couple undergoing PGD with it agree that if a pregnancy ensues from IVF, the mother will undergo prenatal testing in the form of chorionic villus sampling ("CVS") or amniocentesis ("amnio"). (Ex. 18 (Deposition of Mark R. Hughes, M.D., Ph.D. dated 2/19/09) at 36:21 - 42:3.).) CVS is performed in the 11th or 12th week of pregnancy, and amnio is performed between the 14th and 16th weeks of pregnancy -- here, then, this testing should have been completed by October 25, 2004. (Id. at 41:8 - 42:3.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted as to the timing of CVS and amnio testing. The remainder of paragraph 25 is rejected as immaterial, because plaintiffs testified that they told Hughes that they would not undergo such testing, and because, as established by Hughes' deposition testimony (Genesis/Hughes' Exhibit 2, p. 44; Genesis/Hughes'

Exhibit 18, p. 34-38), Genesis/Hughes' interest in such testing was limited to their quality control objectives, and there is "no link" between amnio's "picking up" and affected fetus and abortion; "Amniocentesis is not a search and destroy mission"; and because, as indicated in Dr. Strom's expert report (Genesis/Hughes' Exhibit 25), Genesis/Hughes' quality control objectives could have been satisfied by other means, but Genesis/Hughes manifested no interest in quality control in this case.

PLAINTIFFS' RESPONSE: Plaintiff disputes the content of this paragraph as stated. Plaintiff takes issue with the words, "Genesis has always required that a couple-agree that if pregnancy ensues from IVF the mother will undergo prenatal testing...." While such is the content of a consent form, there is no evidence, except for the testimony of Dr. Hughes on depositions, that Genesis Genetics will refuse to do the laboratory analysis if a couple does not agree to prenatal testing. As is set forth in the Plaintiffs' Supplemental Statement of Material Facts, the credibility of Dr. Mark Hughes' testimony on two depositions is seriously questioned.

GENESIS'S REPLY: Neither Plaintiffs nor NYU cite to any record evidence indicating that Genesis has not always required that a couple undergoing PGD with it agree that if a pregnancy ensues from the IVF, the mother will undergo prenatal testing in the form of chorionic villus sampling ("CVS") or amniocentesis ("amnio") between the 11th and 16th weeks of pregnancy. The testimony cited by NYU speaks for itself, and NYU's conclusions regarding that testimony are rejected as immaterial and unsupported by the record, including NYU's contention that "Genesis/Hughes manifested no interest in quality control in this case." Plaintiffs' questioning of Hughes's credibility without citation to any evidence to the contrary on this issue is not sufficient pursuant to Local Civil Rule 56.1 to place this fact into dispute at summary judgment, and therefore the Court should deem it admitted for purposes of Genesis's Summary Judgment Motion. Regardless, Plaintiffs' and NYU's quibbles are irrelevant to resolving the Genesis's summary judgment motion in Genesis's favor.

27. The Grossbaums gave signed agreements that they would undergo amnio or CVS to both the Genesis defendants and NYU. (Ex. 13 at CG090, CG095.) Despite their written agreements to undergo CVS or amnio, however, it was never the intent of the Grossbaums to follow through on this promise; and, in

fact, Chaya Grossbaum never underwent either amnio or CVS. (Ex. 9 at 79:21 - 81:23; Ex. 8 at 43:12 - 19.) Both Menachem and Chaya Grossbaum testified that they saw no point in having the agreed-upon testing since they were certain that if the results indicated that the child had CF, they would not have aborted it, and that they would rather remain ignorant of the fetus's CF status during the pregnancy than find it out sooner and spend the rest of the pregnancy anxious about the prospect of parenting a child with CF.3 (Ex. 9 at 80:12 - 81:23;Ex. 8 at 48:21 - 51:19.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted that plaintiffs signed the agreements as stated and that they had no intent to and did not undergo CVS or amnio for reasons including those stated. Rejected as immaterial, because abortion was not a requirement of Genesis/Hughes and is not a legal requirement in this case.

PLAINTIFFS' RESPONSE: Not disputed. However, the context of this paragraph is be the subject of further fact presentation in Plaintiffs' Supplemental Statement of Material Facts.

GENESIS'S REPLY: No further response needed other than the fact that Plaintiffs' agreement to undergo CVS or amnio is relevant to the New Jersey statute of limitations argument. (Genesis Summ. J. Reply Br. § III. B._ Genesis has never contended either that "abortion was a requirement of Genesis/Hughes" or that abortion was "a legal requirement in this case."

28. On March 25, 2005, Chaya and Menachem Grossbaum, who remained New York residents, became the parents of Rosie Grossbaum. (Ex. 22 at ¶ 8.) Rosie Grossbaum was born in Denville, New Jersey. Id. About two weeks after her birth, Rosie Grossbaum was diagnosed with CF. (Ex. 27 (Deposition of Chaya Grossbaum, Vol II, dated 3/12/09) at 221:5 - 7.)

NYU RESPONSE: Accepted in part and rejected in part. Rejected, for the reasons stated in paragraph 7 above, that plaintiffs were New York residents when their child was born. The remainder of paragraph 28 is accepted.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: Plaintiffs do not dispute the facts as set forth in this paragraph. NYU's dispute regarding Plaintiffs' residency at the time of Rosie Grossbaum's birth is conclusively resolved in Paragraph 7, which states that Plaintiffs concede that they remained New York residents until five months after Rosie Grossbaum's birth. In fact, Plaintiffs first learned that Rosie Grossbaum had tested positive for a genetic disorder by a letter they received at their home in New York shortly after her birth. (Ex. 27, at 221:5-223:7; 236:1-241:11.) The next day, Chaya Grossbaum spoke by telephone from her New York home with Rosie Grossbaum's pediatrician who informed her that "they believed the issue was cystic fibrosis." (Ex. 27, at 236:1-241:11.) He explained "a little bit about what cystic fibrosis was" and referred her to a specialist. (Ex. 27, at 240:18-241:7.)

29. At some point after Rosie Grossbaum's birth -- but prior to Plaintiffs' March 23, 2007 filing of this lawsuit -- Plaintiffs moved to New Jersey. (Ex. 9 at 9:22 - 10:14.) Plaintiffs filed suit on March 23, 2007 (Ex. 22.) Genesis filed its Answer on September 20, 2007. (Ex. 23 (Answer On Behalf Of Defendants Genesis Genetics Institute, LLC And Hughes, Only).)

NYU RESPONSE: Accepted in part and rejected in part. Rejected, for the reasons stated in paragraph 7 above, that plaintiffs were New York residents when their child was born. The remainder of paragraph 29 is accepted.

PLAINTIFFS' RESPONSE: Not disputed, however see Declaration of Chaya Grossbaum at P1. Exh. 3.

GENESIS'S REPLY: NYU, unlike Genesis, was affirmatively on notice of Plaintiffs' intent to engage a New Jersey midwifery practice and deliver the baby in New Jersey. Ex. 13 at CG 122. *See also* Genesis's Replies to ¶¶ 7 and 28.

II. THE IVF/PGD PROCESS

30. IVF is a process in which the mother takes fertility medications to encourage her ovaries to produce multiple mature eggs at once. (Ex. 13 at CG081 - CG085, ¶ 1.) These eggs are then harvested from the mother. (Ex. 13 at CG081-CG084, ¶ 5.) Each egg is then fertilized with sperm from the father to create an

embryo. (Ex. 13 at CG081-084, ¶ 6.) In typical IVF, one or two of the embryos are implanted into the mother on the fifth day of their existence, the selection of the embryos being dependent upon the extent of their cellular development. (Ex. 13 at CG081-084, ¶ 10.) IVF is typically utilized to overcome fertility problems. (Ex. 13 at CG081-084 (preamble).) If, however, a couple is seeking to avoid a congenital problem, PGD is superimposed upon the IVF process. (Ex. 13 at CG089-092.)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed except that the records referred to support the factual statements do not use the term "typical" to describe the process.

GENESIS'S REPLY: No further response required.

31. Preimplantation genetic diagnosis, as its name implies, involves the diagnosis before implantation of embryos to determine whether the embryo is affected with the disease or condition sought to be prevented, whether it is a carrier of the condition, or whether it is unaffected. (Ex. 13 at CG089-092.) One cell is biopsied from each of the embryos created in the IVF lab, and those individual cells -- one from each embryo -- are then sent to the PGD lab for analysis. (Ex. 13 at CG089-092, ¶ 3.) After the cells are analyzed, their condition is reported to the IVF clinic; and the IVF clinic and the involved would-be parents make a decision as to which embryos, if any, will be implanted. (Ex. 13 at CG089-092 ¶¶ 4, 5; Ex. 13 at CG134; Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23; Ex. 11 (Deposition Transcript of Dr. Frederick Liccardi, dated 3/11/09) at 62:18 - 63:17.) This decision takes into account both the analysis of the biopsied cells and the quality of the embryos. (Ex. 9 at 154:13 - 156:6; Ex. 8 at 61:9 - 23.)

NYU RESPONSE: Accepted.

PLAINTIFFS' RESPONSE: Not disputed except to the extent that the "would be parents make a decision as to which embryos, if any, will be implanted," Plaintiffs dispute the extent to which the Plaintiffs were informed at the time of implantation of the deficiencies in the embryos that were sent to Genesis Genetics for analysis and the implications of the report of Genesis Genetics with respect to the increased risk of misdiagnosis.

GENESIS'S REPLY: No further response required.

32. In early-to-mid 2004, when the events occurred that are the subject of this case, there were approximately eight laboratories in the United States that were doing PGD. (Ex. 1 (Deposition of Dr. Charles Strom, Vol. I, dated 5/4/10) at 112:7-8, 15-16, 18-23; 113:2 - 16.) Only a few of these laboratories, however, were performing PGD analyses in any significant volume. (Ex. 18 at 26:17 - 25.) PGD was then, and is now, a highly sophisticated, rapidly evolving technology. There are thousands of genetic mutations; and it is necessary to devise a separate PGD test for each such mutation, often in an extremely short period of time. Id. at 31:14 - 33:17.)

NYU RESPONSE: Accepted, but subject to the understanding that Genesis was a high-volume and leading PGD laboratory.

PLAINTIFFS' RESPONSE: Disputed. This paragraph, purported to be a statement of undisputed material facts, is a compilation of hearsay information obtained from the experts of both Plaintiffs and the Defendants. In addition, reference to the statement, "only a few of these laboratories," is vague and undefined. Also, a description of significant volume is a subjective and non-factual conclusion. In addition, the statement that "there are thousands of genetic mutations: and it is necessary to devise a separate PGA for each such mutation often in an extremely short period of time" is irrelevant and not material to the inquiry herein. As seen from Plaintiff's Statement of Material Facts, the mutations carried by the Plaintiffs were well known, well defined and were capable of PGD analysis by the Defendants' laboratory. The fact that there may be other mutations has no bearing on the testing done for the Plaintiffs.

GENESIS'S REPLY: Genesis does not dispute that it was a high-volume and leading PGD laboratory. To the extent that Plaintiffs substantively dispute Genesis's statements, they cite to no record or other competent evidence to the contrary, and therefore Genesis's statement of undisputed material facts should be accepted by the Court as true for purposes of this motion, as required by Rule 56.1 which requires the opponent to a summary judgment motion to state "each material fact in dispute and cit[e] to the affidavits and other documents submitted in connection with the motion."

Rule 56.1 provides that "any material fact not disputed shall be deemed undisputed for purposes of the summary judgment motion."

33. There were two primary ways in which labs in the United States did PGD in early-to-mid 2004. (Ex. 13 at CG089-092, ¶ 4.) All but one lab, including Genesis, routinely performed PGD with single cell testing. (Ex. 6 at ¶ 10; Ex. 5 (Expert Report of Kangpu Xu, dated 2/26/10) at 2.) One laboratory, Reproduction Genetics Institute ("RGI"), performed multiplex (or genetic marker) testing. (Ex. 6 at ¶ 10.) Multiplex testing was in its infancy in the United States at that time. Id. It involves obtaining one embryonic cell after IVF, and then comparing the cell with cells taken from other family members of the involved couple. (Ex. 2 (Deposition of Mark R. Hughes, dated 5/14/10) at 49:17 - 54:20.) Various other laboratories, including Genesis, were trying to develop this technology in America; but as of the dates in question, the success rate they achieved in trial runs was not sufficiently high for the technique to be used on a regular basis. (Id.; Ex. 6 at ¶ 9, 10.)

NYU RESPONSE: Accepted in part and rejected in part. Accepted that, in 2004, at least one PGD lab in the United States used multiplex or genetic marker testing and that Genesis did not. The remainder of paragraph 33 is rejected, because the feasibility and success of such testing is a question of fact on the record of this case, given the conflicting testimony of the respective experts on that issue, and given the inherent question of the experts' credibility, which is a matter for the fact-finder to determine; because Genesis/Hughes' head-counting analysis does not establish the standard of care; and because the feasibility and use of such testing may be legally irrelevant to the questions of duty and causation as to Genesis.

PLAINTIFFS' RESPONSE: Disputed:

(a) The statement, "all but one lab including Genesis, routinely performs PGD with single cell testing," is unintelligible and its materiality is unknown. Also, "all but one lab" does not assist the fact finder in understanding the meaning of that reference. The source material for that statement in referring to the sworn declaration of Dr. Hughes (Genesis Exhibit 6) at Paragraph 10 is categorically refuted by his own deposition testimony on 2/19/09 at T:57-8 to 57-25; Pl. Exh. 6. The second reference for the statement is an expert report which contains the opinion and hearsay statements of Defendants' expert, Dr. Kangpu Xu.

(b) The statement, "One laboratory, Reproductive Genetics Institute, performed multiplex or genetic marker testing" is again a statement supplied by the Defendant Dr. Mark Hughes in his expert capacity. Again, this constitutes hearsay statement by Dr. Hughes.

The statement "multiplex testing was in its infancy in the United States at that time" is a conclusionary statement and self-serving by Dr. Hughes.

The apparently hearsay testimony of Dr. Hughes is refuted by the statements made by Dr. Strom, which will be addressed in Plaintiffs' Supplemental Statement of Material Facts.

GENESIS'S REPLY: Both NYU and Plaintiffs fail to cite to competent evidence to support their disputes of Genesis's statements in Paragraph 33. NYU states without citing to the record that the experts in this case have disputes as to this issue. Plaintiffs claim that Plaintiffs' Ex. 6 provides evidence that is contrary to that provided in Mark Hughes's Declaration. As set forth in Genesis's Response to Plaintiffs' Supplemental Statement of Undisputed Material Facts at ¶ 11, supra, the alleged contradiction between Hughes's declaration and testimony is fully resolved by presenting the full context of the February 2009 testimony given by Mark Hughes.

34. Dr. Kangpu Xu ("Xu"), the retained liability expert for the Genesis defendants, was actively involved in the PGD laboratory at Weill Cornell School of Medicine in New York City at the time the incidents that form the subject matter of this lawsuit took place. (Ex. 5 at 1-2.) Dr. Xu opined that using linkage markers (another term for multiplex testing) was not the standard of care in 2004. (Id. at 2.) Indeed, he explained that during the relevant time period, those linkage markers were not necessarily used, even where the risk of misdiagnosis was significantly higher than that faced by the Grossbaums:

> Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome disorder with 50% risk without using markers. The

> reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 different IVF-PGD attempts. I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.

(Id. (emphasis added).)

NYU RESPONSE: Rejected for the reasons stated in paragraph 33 above.

PLAINTIFFS' RESPONSE: Disputed. On its face, this paragraph contains statements of opinion and not statements of undisputed material facts.

GENESIS'S REPLY: Both NYU and Plaintiffs fail to cite to competent evidence, as required by Local Civil Rule 56.1, to support their efforts to dispute Genesis's statements in Paragraph 33. Therefore, Genesis's statements should be deemed admitted for the purposes of this motion. NYU's statements the experts in this case have disputes as to this issue, without competent record citations as required by Local Civil Rule 56.1, is not sufficient to prevent this Court from deeming this Paragraph admitted for purposes of Genesis's Summary Judgment Motion.

35. The failure rate of single cell PGD was less than five percent (5%) in early-to-mid 2004, although Genesis enjoyed a far smaller failure rate, in the area of two percent (2%) or less. (Ex. 18 at 31:3 - 13.) The main problem with single cell testing was that it was difficult to predict allele drop out ("ADO"), a known complication in PGD. (Ex. 2 at 33:6 - 19; Ex. 5 at 2.) During their telephone conversation with Dr. Hughes, the five percent rate was quoted to the Grossbaums, and they were otherwise fully informed as to the nature and risks of PGD. (Ex. 9 at 120:15 - 121:12, 171:4 - 172:9; Ex. 8 at 32:14 - 16; Ex. 16 (Deposition of Dr. Kangpu Xu, dated 5/13/10) at 100:12 - 25, 101:13 - 16, 101:23 - 25, 102:1 - 25, 103:1 - 5; Ex. 13 at CG093-CG097, ¶ 5, 6.)

NYU RESPONSE: Accepted in part and rejected in part. Rejected that the failure rate of single cell PGD was less than 5% in early-to-mid 2004 and

that Genesis' rate was then lower, because the reports and testimony of some of the experts in this case such as Hughes and Dr. Strom present a material question about the accuracy of the quoted success rate, and because the quoted success rate may be legally irrelevant in this case. Rejected that "predicting" ADO was a problem, because that statement is not supported by the cited references, and because ADO was detectable by single-cell PGD, but was detected and reported by Genesis/Hughes only with respect to embryo 2 in this case. Rejected that Hughes quoted only the 5% rate to plaintiffs, because, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, Hughes quoted an error rate of 2-3% PGD error rate at Genesis to plaintiffs; plaintiffs agreed to proceed with IVF and PGD processes based upon that rate and not upon the 10% rate provided by NYU; and that plaintiffs would not have decided to proceed if the error rate or risk provided by Hughes had been higher than 2-3%. Accepted, with the exceptions noted above in this paragraph, that plaintiffs believed and Dr. Xu opined that Hughes otherwise fully informed plaintiffs about the nature and risks of the PGD process to be conducted by Genesis/Hughes

PLAINTIFFS' RESPONSE: Disputed for the following reasons:

(a) The statement that "the failure rate of single cell PGD was less than 5% in early to mid 2004" is unsupported by any reference to any published statistical data and therefore, not capable of being established by competent factual evidence;

(b) "Genesis enjoyed a far smaller failure rate in the area of 2% or less" is actually less than 1% as admitted by Dr. Hughes in his deposition of 2/19/09 (see Genesis Exh. 18 at T:31-3 to 31-13);

(c) The statement that "the main problem with single cell testing was that it was difficult to predict allele dropout, a known complication in PGD" again relies on the opinion testimony of the Defendant, Dr. Hughes, as well as the opinion of Dr. Xu, Defendant's expert. Learned treatises brought to the depositions and provided to the Defendant, as more particularly set forth in Plaintiffs' Supplemental Statement of Material Facts, indicate that the mutations of the Plaintiffs, Chaya and Menachem Grossbaum, called compound heterozygous mutations, have a higher risk of ADO than other single cell mutations for cystic fibrosis.

(d) In addition, during the telephone conversation with Dr. Hughes, there is a serious factual dispute as to whether the 5% number was used by Dr. Hughes. In any event, the numerical and statistical information was made insignificant by Dr. Hughes' conversation with the Grossbaums as they reported in their depositions as cited (Genesis Exh. 9 at T:120-15 to 121-12). Chaya Grossbaum testified as follows:

Q So you had your conversation with Dr. Hughes before you read and signed this document. Correct?

A Yes.

Q So was you - are you saying it was your] understanding from Dr. Hughes that there was a success rate better than 90 percent?

A Yes.

Q And can you be any more specific about what you said before, that there had been hundreds of people and 10 or 11 errors?

A Yes. He said that although he can't guarantee it because nothing is guaranteed, that it was very unlikely that it would be a mistake, and he also specified within cystic fibrosis, because we had more common mutations, that it should be even less difficult to do it properly because it was a more common condition, more common mutations, and that he wasn't going to guarantee anything because nothing is guaranteed, but that the risks of it not being a success were very slim, and it was a very high chance of it being successful.

In addition, the deposition testimony of Dr. Kangpu Xu is purely hearsay on the subject.

GENESIS'S REPLY: Hughes testified that "Yeah, we'll tell them -- the field of PGD quotes a risk of 3 to 5 percent error for this kind of testing" (Ex. 18 at 31:4-5), so Plaintiffs' and NYU's contention that Hughes quoted Plaintiffs an error rate of less than 2% is not supported by the record. Genesis does not dispute that its actual error rate was as stated by Dr. Hughes in his February 19, 2009 Deposition. Plaintiffs' statements that certain facts supported by Hughes's and Xu's testimony are not admissible on this basis does not accurately reflect the standard for evaluating

undisputed material facts submitted to the Court pursuant to Local Civil Rule 56.1. Furthermore, Plaintiffs' citation to Chaya Grossbaum's testimony, which is silent on what error rates Hughes reported on a percentage basis, does not contradict the facts as set forth by Genesis. NYU's attempts to dispute this paragraph, which do not cite to a single source in the record, do not comply with this Court's requirements for disputing statements of undisputed material facts submitted pursuant to Local Civil Rule 56.1.

36. The plaintiffs' liability experts, Dr. Charles Strom ("Strom") and Dr. Garry Cutting ("Cutting"), have both testified that the standard of care required that defendants Hughes and Genesis perform genetic marker, or multiplex, testing in the PGD done for the Grossbaums, and that their failure to do so was the likely proximate cause of the infant plaintiff being born with cystic fibrosis. (Ex. 24 (Expert Report of Dr. Garry R. Cutting, dated 9/29/09) at 3; Ex. 25 (Expert Report of Dr. Charles M. Strom, dated 11/12/09) at 2.) Cutting, however, testified at his deposition that Strom miscalculated the increased failure risk associated with the fact that Genesis did not use multiplex testing with the Grossbaums. (Ex. 15 (Deposition of Dr. Garry Cutting, Vol. II, dated 11/8/10) at 283:2 - 7.)

NYU RESPONSE: Rejected, because the reports and testimony of the plaintiffs' experts indicate that Genesis/Hughes may have misread or misstated in their PGD report the genetic suitability of the implanted embryos regardless of the nature of the test performed; because the reports and the testimony of the various experts indicate that Hughes failed to quote the accurate risk of misdiagnosis and development of a CF-affected child to the plaintiffs; and, because the feasibility and use of multiplex or marker testing may be legally irrelevant to the questions of duty and causation as to Genesis.

PLAINTIFFS' RESPONSE: The testimony of Plaintiffs' liability experts is not disputed. The additional statement of "Cutting however testified at his deposition that Strom miscalculated the increased failure risk associated with the fact that Genesis did not use multiplex testing with the Grossbaums" is again opinion and subject to question.

GENESIS'S REPLY: NYU failed to cite to any competent evidence as required by Local Civil Rule 56.1. Thus, this Court should reject NYU's

attempts to characterize this paragraph as containing disputed statements of material facts. No further response is needed to Plaintiffs' response to this paragraph.

37. At the time in question, only RGI was regularly doing multiplex testing for cystic fibrosis in the United States. (Ex. 1 (Deposition of Dr. Charles Strom, Vol. I, dated 5/4/10) at 122:2 - 23; Ex. 4 (Deposition of Dr. Garry R. Cutting, Vol. I, dated 4/24/10) at 156:3 - 25, 157:1 - 25, 158:1 - 4, 161:10 - 25, 162:1 - 21.) Literature in Europe suggested that this technique was promising, but the average reasonably prudent PGD lab in America was not performing such testing. (Ex. 2 at 47:4 - 49:3.) At his deposition, Hughes explained that the fact that a few papers had been published touting the advantages of multiplex testing did not instantly establish such testing as the new standard for mainstream clinical practice in the United States, given that such results needed to be validated. (Ex. 18 at 47:4 - 48:17.) Indeed, with the exception of RGI, Plaintiffs have not offered any evidence of what the standard practice was at the other U.S. PGD laboratories. (Id. at 48:18 - 49:3; see generally Ex. 1, Ex. 3, Ex. 4, Ex. 15 (Deposition of Dr. Garry Cutting, Vol. II, dated 11/8/10).)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. This fact, although not material, was clearly not a fair interpretation of the cited depositions of Plaintiffs' experts, Dr. Charles Strom and Dr. Garry R. Cutting for the following reasons:

(a) Although RGI was indentified as doing the multiplex, these witnesses did not have knowledge of what was being done at other laboratories and therefore, it is inappropriate to draw affirmative factual conclusions suggested by the Defendants based on the deposition testimony of these witnesses.

(b) The statement regarding the literature in Europe is the opinion testimony of the Defendant, Dr. Mark Hughes, and is belied by the information reported in the literature from the European laboratories as more particularly referred to in Plaintiffs' Supplemental Statement of Material Facts.

(c) Further statements by Dr. Hughes contained in this paragraph are pure hearsay opinion testimony.

(d) The statement, "indeed with the exception of RGI, Plaintiffs have not offered any evidence of what standard practice was at other PGD laboratories," is argumentative and not a statement of undisputed material fact.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with the requirements of Local Civil Rule 56.1.

III. ADDITIONAL FACTS PERTINENT TO THE DAUBERT MOTION, WHICH, IF GRANTED, WOULD REQUIRE THIS COURT TO GRANT SUMMARY JUDGMENT IN GENESIS'S FAVOR[3]

38. Dr. Charles Strom, plaintiffs' retained liability expert against Defendants Genesis and Hughes, stated in his deposition that as of 2004, there were no more than eight laboratories in the United States that were performing preimplantation genetic diagnosis (PGD): 1) RGI, in Chicago; 2) Reprogenetics, in New Jersey, 3) Genetics and IVF, in Virginia; 4) Cornell Medical Center, in New York City; 5) Genesis Genetics, in Detroit; 6) Shady Grove, in North Carolina; 7)

[3] **Footnote Inserted By NYU States:** Genesis/Hughes' *Daubert* motion seeks to prevent plaintiffs' experts from testifying about the feasibility and use of multiplex or marker PGD testing in 2004, but those experts could address other issues pertinent to the questions of duty and causation on the part of Genesis/Hughes. Consequently and contrary to Genesis/Hughes' mistaken assertion, the Court's grant of Genesis/Hughes' *Daubert* motion does not require the Court to grant Genesis/Hughes' motion for summary judgment. **GENESIS'S REPLY:** It is NYU that is mistaken. If Plaintiffs' experts are disqualified at least to the extent that they provide Plaintiffs' only evidence establishing the standard of care, then even if New Jersey law applies, this case must be dismissed against Genesis, as Plaintiffs will not be able to prove what the standard of care was (much less that Genesis violated it) and therefore cannot establish the first element of their wrongful birth and wrongful life claims.

Baylor University; 8) a lab whose name he does not know, in Florida. (Ex. 1 at 112:7 - 8, 15-16, 18-23; 113:2 - 16.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. Dr. Charles Strom did not state in his deposition that there were no more than eight laboratories in the United States that were performing pre-implantation genetics diagnosis. The citation does not support the conclusionary statement of material facts applied by the Defendants.

GENESIS'S REPLY: Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

39. Strom testified that except for Genesis, which he knows from the discovery in this case was not doing multiplex testing in 2004, and RGI, he does not know if any of the other labs mentioned above were doing multiplex testing. (Ex. 1 at 122:2 - 23.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. Dr. Strom testified that his only knowledge of laboratories in the United States was that RGI was doing multiplex testing, but Dr. Strom's reference to Genesis Genetics' deposition offerings is a conclusion and not a statement of fact as to whether Genesis was able to do multiplex testing.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

40. The only lab Strom knows "for sure" that was doing testing with multiplex genetic markers in 2004 was RGI; and he is not specifically aware of any other lab that was using this technology at the time. (Ex. 1 at 84:25, 85:1 - 10.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

41. Strom asserted that in 2004, RGI, which he believed to be doing multiplex testing, was "providing probably over half the services for PGD in the country at the time." (Ex. 1 at 121:7 - 20.) The fact that is undisputed is that Strom made this assertion, not that it is true, nor that the volume any given lab has in any way governs the standard of care.

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: This statement of Plaintiffs' expert was opinion testimony in a deposition and not a statement of material facts regarding the issues in this case.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

42. Strom testified that when he was connected with RGI, from 1992 to 2000, he was the person doing PGD for that institution. During that "eight-year span," he performed "probably a couple of hundred" PGD analyses for cystic fibrosis. (Ex. 1 at 50:21 - 25, 51:1 - 3.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1's requirements.

43. Strom testified that these PGD analyses resulted in "probably thirty births, I would guess. Thirty to forty births." (Ex. 1 at 51:4 - 9.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

44. Per contra, Genesis has done 582 PGD cycles or tests in the calendar year 2004 alone. (Ex. 2 at 43:10 - 25, 44:1.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. Use of the term "per contra" is argumentative. Moreover, Defendants' statement compares apples and oranges: Strom's testimony was related to births. This paragraph refers to PGD cycles, which may or may not have resulted in births.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

45. Strom testified that he is currently employed by Quest Diagnostics. He started working at Quest in October, 2000. (Ex. 1 at 20:12 - 20.) Strom testified that neither he nor Quest has been engaged in PGD during the time that he has been employed there. (Ex. 1 at 22:18 - 22, 26:3 - 6.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

46. Strom testified that he teaches "everything genetics" at University of California San Diego ("UCSD"), that he "sometimes" touches on PGD in his lectures at UCSD, and that his teaching involving PGD is "probably less than five percent." (Ex. 1 at 22:23 - 25, 23:1 - 14.) Strom testified that while "some" of his lecturing outside of teaching involves PGD, this percentage is about two to three percent. (Ex. 1 at 23:15 - 25, 24:1 - 18.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Not disputed, although its materiality is subject to question.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

47. Strom testified that he has given about a dozen depositions, but none in PGD or IVF cases, nor has he given a deposition in any case involving cystic fibrosis. (Ex. 1 at 16:24 - 25, 17:1 - 16.) The only wrongful birth case in which Strom has testified involved serum screening, an issue not involved in this case. (Ex. 1 at 17:17 - 25, 18:1 - 3). He has, therefore, never been certified or deemed qualified by a Court to testify as an expert as to issues involving PGD.

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Not disputed, but questioned as a statement of a material fact. This is a clear example of what one can characterize as "sly" representation of a material fact. The mere statement that he has not been certified or deemed qualified by a court does not in any way impair his qualifications.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1's requirements. To the extent that Plaintiffs' characterize Genesis's language as "sly," Genesis rejects the characterization and notes that the language in the paragraph is substantively undisputed and speaks for itself.

48. Strom testified that in formulating his opinions as to the alleged breach of the standard of care by defendants Hughes and Genesis, he does not limit his definition of that term to the United States. (Ex. 1 at 69:23 - 25, 70:1 - 9.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. This statement is unintelligible. Is the Defendant arguing that the standard of care is different in the United States than in Europe? If Strom knew the standard of care in Europe as well as in the United States, what is the materiality of that fact?

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1's requirements. Plaintiffs' rejection of this statement as "unintelligible" is itself nonsensical. As stated in the cited testimony, Strom's testimony was that in determining the "standard of care" applicable to defendants' actions, Strom did not limit his analysis to the prevailing standard in the United States, but rather embraced a worldwide standard in making this determination. (Ex. 1 at 69:23-25; 70:1-9.)

49. The only materials Strom has reviewed in preparation for formulating his opinions in this case are the records of Genesis, and transcripts of the depositions of Hughes, Dr. Garry Cutting ("Cutting"), and Dr. Kangpu Xu ("Xu"). He has not been provided with the records of NYU, or with transcripts of the depositions of any of the other witnesses in the case, including the adult plaintiffs and the various NYU personnel. (Ex. 1 at 8:12 - 25, 9:1 - 7, 13:20 - 25, 14:1 - 25, 15:1 - 25, 16:1 – 6.) (Ex. 3 at 166:4 - 19.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: This is not a statement of material fact, but an argument regarding the Defendant's claims as to the thoroughness of the Plaintiff's expert, which will be a matter of dispute at the time of trial.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1's requirements. Plaintiffs do not dispute that the transcript reflects that their statement of undisputed material facts accurately reflects which transcripts and case documents were and were not provided to Dr. Strom.

50. Strom testified that the standard of care did not require that polar biopsy be done or offered in 2004. (Ex. 3 at 167:8 - 25.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

51. Cutting is a liability expert retained by the plaintiffs to offer opinions primarily against NYU; but he has additionally offered opinions critical of defendants Hughes and Genesis. By way of education, background and training, Cutting is a board certified pediatrician. His fellowship training is in medical

genetics, which involves the "care, diagnosis. . . and treatment of patients with a variety of genetic disorders." This is to be distinguished from PGD, which is concerned with the prevention of such disorders before implantation of embryos in an in vitro fertilization setting. (Ex. 4 at 10:18 - 25, 11:1 - 23.)

NYU RESPONSE: Accepted in part and rejected in part. Rejected that Cutting was retained primarily to offer an opinion against the NYU defendants, because, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, Cutting viewed his purpose in this case as "offering an expert opinion on diagnostic procedures in PGD." The remainder of paragraph 50 is accepted, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, and their motion for summary judgment, Cutting is not qualified to testify against the NYU defendants and such testimony should be precluded by the Court.

PLAINTIFFS' RESPONSE: Disputed:

(a) Dr. Cutting was an expert retained by Plaintiff to inform and educate Plaintiffs' counsel as to the medicine involved in the genetics of this case, and not solely as to offer opinions primarily against NYU. This is certainly not a statement of material fact to the case.

(b) Defendant's statement in this paragraph that "this is to be distinguished from PGD" is argumentative and not a statement of fact as to the limitations of Dr. Cutting's training and experience.

GENESIS'S REPLY: Strom was retained by the Plaintiffs to testify solely against Genesis. In his deposition, the chief criticisms voiced by Cutting were against NYU. He is the only expert retained by Plaintiffs to testify against NYU; so he is, therefore, the Plaintiffs' primary witness against NYU. As to Genesis, Cutting's only criticism was that Genesis failed to utilize multiplex testing. (Blaine Decl. Ex. 4 at 157:15-24.) However, Cutting readily acknowledged that he had no idea what the average reasonably prudent PGD lab in America was doing by way of testing. Accordingly, and because he was never directly involved in PGD until well after the dates in question in this case – and then only on two very limited occasions, and for other reasons set forth in the Motion to Strike Plaintiffs'

Liability Expert papers filed by Genesis, Cutting is not qualified to testify against Genesis.

52. Cutting is not now involved directly in performing PGD. (Ex. 4 at 117:12 - 25.) Similarly, Cutting was not directly involved in PGD in the year 2004. (Ex. 4 at 118:1 - 11.) In his entire career, Cutting has been directly involved in only two (2) PGD cases, which took place "[p]robably more than 12 months ago, but not more than three years ago." (Ex. 4 at 117:12 - 25, 118:1 - 25, 119:1 - 7.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, and their motion for summary judgment, Cutting is not qualified to testify against the NYU defendants and such testimony should be precluded by the Court.

PLAINTIFFS' RESPONSE: Not disputed except to note the use of the term "directly" as a qualifier in the entire statement contained in this paragraph.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

53. At the time of his deposition, Cutting believed that there were two (2) or three (3) labs in the United States doing PGD. (Ex. 4 at 123:4 – 5.) Cutting has never been a member of the PGD International Society or any PGD group of scientists in the United States, Canada, or elsewhere in the world. (Ex. 4 at 146:18 - 23.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, and their motion for summary judgment, Cutting is not qualified to testify against the NYU defendants and such testimony should be precluded by the Court.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

54. Cutting is aware that RGI was doing multiplex testing for cystic fibrosis in 2004; but he does not know what was being done by Reprogenetics in New Jersey or by Cornell Medical Center in 2004, and he had never heard of Genetics and IVF in Virginia. (Ex. 4 at 156:3 - 25, 157:1 - 25, 158:1 – 4.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, and their motion for summary judgment, Cutting is not qualified to testify against the NYU defendants and such testimony should be precluded by the Court.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

55. Cutting does not know whether in early to mid-2004, the average PGD provider in the United States with reasonable skill and care was using genetic markers for testing for cystic fibrosis in individuals undergoing PGD. (Ex. 4 at 161:10 - 25, 162:1 – 21.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, and their motion for summary judgment, Cutting is not qualified to testify against the NYU defendants and such testimony should be precluded by the Court.

PLAINTIFFS' RESPONSE: Disputed. This statement does not accurately reflect the testimony of Dr. Cutting.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

56. The only materials Cutting has reviewed in preparation for formulating his opinions in this case are the records of Genesis; the records of NYU; various articles; and transcripts of the depositions of Hughes, Dr. Frederick Licciardi ("Licciardi"), and Embryologist Alexis Adler ("Adler"). He has not been provided with transcripts of the depositions of any of the other witnesses in the case, including the adult plaintiffs and various other NYU personnel. (Ex. 4 at 50:2 – 22.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, and their motion for summary judgment, Cutting is not qualified to testify against the NYU defendants and such testimony should be precluded by the Court.

PLAINTIFFS' RESPONSE: Disputed as a statement of material fact. This is argumentative as to the qualifications of Dr. Cutting to offer opinions regarding this case and the suggested conclusions are invalid and subject to trial events.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

57. Cutting testified that the standard of care did not require that polar biopsy be done or offered by defendants Genesis or Hughes in 2004. (Ex. 4 at 181:6 - 25; 182:1.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above, but subject to the understanding that, as established by the NYU defendants' Local Rule 56.1 statement and its supporting evidence, and their motion for

summary judgment, Cutting is not qualified to testify against the NYU defendants and such testimony should be precluded by the Court.

PLAINTIFFS' RESPONSE: Not disputed.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1.

58. Xu, the retained liability expert for defendants Genesis and Hughes, was actively involved in the PGD laboratory at Weill Cornell School of Medicine in New York City at the time the incidents that form the subject matter of this lawsuit took place; and he has stated that Cornell did not routinely utilize multiplex testing at that time, and that the use of multiplex testing was not required by the standard of care in 2004:

> Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome disorder with 50% risk without using markers. The reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 different IVF-PGD attempts. I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.

(Ex. 5 at 2.) (Emphasis added.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. As indicated in Response to #34, this reference is to the expert report of Defendants' expert Dr. Kangpu Xu which contains opinion and hearsay statements and has been the subject of question as to its veracity. In addition, he was specifically asked on his deposition:

Q. And is it possible that you were doing linkage analysis for cystic fibrosis in early 2004?

A. I don't remember if we did.

Q. Are you able to say definitely that you did not do linkage analysis for cystic fibrosis in the year 2003?

A. No, I can't say definite.

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1. To the extent that Plaintiffs rely on testimony they claim contravenes this Paragraph 58, the deposition testimony speaks for itself. As determined by this Court and Magistrate Judge Salas on numerous occasions, Plaintiffs have proffered no competent evidence whatsoever that the "veracity" of Dr. Xu's report can reasonably disputed. See, e.g., Oct.. 6, 2010, Memorandum Opinion, at 4 (Docket # 99)

59. During his entire career in the field of PGD, Hughes has constantly monitored the scientific literature and best practices at the other laboratories that provide PGD as well as stayed active in PGD-related professional organizations and attended PGD-related conferences (often as a speaker, panelist, or other presenter) in an effort to ensure that the PGD services provided by the laboratories he has been associated with, including Genesis, have incorporated all proven technological advances into the services they offer to couples. He has also been a member in good standing of the Preimplantation Genetic Diagnosis International Society and President of the PGD-SIG of the American Society of Reproductive Medicine, the foremost organization in this field. (Ex. 6 at ¶ 8.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. This is a self-serving, non-material statement by Dr. Hughes, which is not relevant and not a statement of undisputed material facts.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

60. Because the PGD field is constantly evolving and changing, scientists are constantly publishing articles describing the latest technology trials. Publication of an article in the scientific literature describing a possible advance in PGD technology or techniques does not dictate that the PGD laboratories will immediately change their standard practices: first, the results provided by the new technology or technique must be replicated repeatedly, over time; second, evidence must be collected demonstrating that the new technology or technique provides a significant benefit and no harm over the previous methodology; and finally, the technology or technique must be refined and adapted as necessary to be commercially viable. The length of time between publications and clinical implementation of a medical technique often requires several years. (Ex. 6 at ¶ 9.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. This abstract statement by Dr. Hughes in his self-serving declaration is not material to the issues in the case. The dispute may be focused on the direct testimony of Dr. Strom in depositions. Dr. Strom has been identified as the leading developer of the PGD techniques for cystic fibrosis in his deposition. He stated:

Q. [By Mr. Leuchtman] What do you think even generally as we sit here right now are the areas of disagreement that you had with Dr. Hughes' opinions?

A. The one I recall most was his assertion that the use of linked makers for protection of ADO was not well established at the time. I take exception with that.

(Strom Dep. 6/24/10 at T:180-10 to 180-16; Pl. Exh. 19.)

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1. To the extent, if any, that Dr. Strom's testimony disagrees with this Paragraph 60, the deposition testimony speaks for itself.

61. In 2004, Genesis was not performing multiplex DNA amplification of genomic markers for clinical PGD. Genesis had seen the results published by RGI of Chicago, but had had trouble replicating them in its laboratory. Furthermore, Genesis' error rate without using multiplex markers was significantly lower than the industry average reported error rate. Finally, while Genesis was aware that RGI in Chicago was providing multiplex testing to couples at the time, Genesis agreed with Xu and others that the evidence did not yet support offering multiplex testing as the standard of care. (Ex. 6 at ¶ 10.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. This statement by Dr. Hughes is categorically refuted by his own deposition testimony. (See Hughes Dep. 2/19/09 T:57-8 to 57-25; P1. Exh. 6.)

GENESIS'S REPLY: NYU has failed to cite to any competent record or other evidence in support of its rejection of this paragraph, which therefore must be deemed admitted as to it in accordance with Local Civil Rule 56.1. See Genesis's Reply to ¶ 33 and Genesis's Reply to Plaintiffs' Supplemental Responses ¶ 11, which set forth the full context of Dr. Hughes's deposition testimony, as excerpted by Plaintiffs. The full deposition testimony refutes Plaintiffs' rejection of this Paragraph 61.

62. At his deposition, Strom identified laboratories that he said were performing PGD in early-to-mid 2004. The laboratories he identified were:

- "RGI in Chicago" (Ex. 1, Strom Dep., 5/4/10, p. 112:7 - 8);
- "Reprogenetics in New Jersey" (Ex. 1 at 112:15 - 16);
- "Genetics and I.V.F. in Virginia" (Ex. 1 at 112:18 - 20);

- "Cornell Medical Center in New York City" (Ex. 1 at 112:21 - 23);
- "Shady Grove" of "North Carolina" (Ex.1 at 113:2 - 16);
- "Baylor" (Ex. 1 at 113:2 - 12); and
- "a lab in Florida that was trying to develop P.G.D." (Ex. 1 at 113:9 - 12).

(Ex. 6 at ¶ 11.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. The representation of the meaning of the witness' testimony as cited by this Defendant is totally inconsistent with any fair reading of the deposition testimony. The question specifically related to laboratories advising couples as to the nature of allele dropout. The witness did riot know whether the laboratories that were mentioned by the Defendant in the questioning were giving such advice. That specifically is not testimony supporting the identification of laboratories that were performing PGD.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1. The deposition testimony cited by Genesis speaks for itself.

63. Strom's testimony betrays not only his lack of knowledge regarding the standard of care at United States PGD laboratories in 2004, but also displays that he was not even aware of which laboratories were performing PGD at that time. For instance, Shady Grove (of Washington, D.C., not North Carolina) was not independently performing PGD in 2004, but instead was sending all of its PGD work to Genesis at that time. (Ex. 6 at ¶ 12.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. This is not undisputed material factual content. This is argumentative and has no logical connection to the expert witness' knowledge of the standard of care in 2004.

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

64. From Hughes' active participation in the PGD community and interaction with professionals at these institutions, he is familiar with the practices of these laboratories in the 2004 time frame. To the best of his knowledge, in July of 2004, when Genesis performed its study of the Grossbaums' embryos, the only United States laboratory that routinely offered multiplex testing to its patients was RGI of Chicago, Illinois. In particular, from Hughes' previous association with the Prenatal Genetics Center at Baylor, he is aware that Baylor was not routinely providing multiplex testing in early-to-mid 2004. (Ex. 6 at ¶12.)

NYU RESPONSE: Rejected for the reasons stated in paragraph 36 above.

PLAINTIFFS' RESPONSE: Disputed. Not a statement of material fact and is of no relevancy as to "whether Dr. Hughes was `aware that Baylor was not routinely providing multiplex testing in early to mid 2004.1"

GENESIS'S REPLY: Both Plaintiffs and NYU have failed to cite to any competent record or other evidence in support of their rejection of this paragraph, which therefore must be deemed admitted as to them in accordance with Local Civil Rule 56.1.

PLAINTIFFS' SUPPLEMENTAL RESPONSES

1. This case involves the application of two scientific developments, in-vitro fertilization and preimplantation genetic diagnosis–the opportunity to study the genetic make-up of an embryo (a fertilized egg) to determine the presence of genetic disorders prior to implantation in the mother's womb to create pregnancy and ultimately, the birth of a health child. Facts surrounding in-vitro fertilization well recognized in public discourse and preimplantation genetic diagnosis were described in the year 2000 in the textbook entitled "An Illustrated Textbook and

Reference for Clinicians; An Atlas of Preimplantation Genetic Diagnosis" at Page 11:

> Preimplantation genetic diagnosis (PGD) is a principally new approach for the prevention of genetic disorders, which avoids the need for prenatal diagnosis and termination of pregnancy. It is based on control of the processes of oocyte maturation, fertilization and implantation, to select and transfer back to the uterus only normal embryos, and achieve an unaffected pregnancy and the birth of a health baby. In this way, couple at high risk of having offspring with genetic disease will have an option to control the outcome of their pregnancy from the very outset. Although this option involves ovarian hyperstimulation and in vitro fertilization (IVF), available experience shows that PGD appears to be an acceptable procedure in many ethnic groups all over the world. (Pl. Exh. 1.)

GENESIS'S REPLY: Not disputed to the extent that IVF and PGD, when used together, are intended to decrease the likelihood that a woman who is a carrier for a genetic disorder will give birth to a child who is affected with that disorder. Disputed to the extent that Plaintiffs rely on their citation to "An Illustrated Textbook and Reference for Clinicians; An Atlas of Preimplantation Genetic Diagnosis" to establish "facts" that were "well recognized in public discourse and preimplantation genetic diagnosis" in the year 2000. The text cited by Plaintiffs was published by former colleagues of Plaintiffs' liability expert, Dr. Charles Strom, at Reproductive Genetics Institute of Chicago, Illinois and therefore Plaintiffs' characterization of this text as establishing well-recognized "facts" is open to debate. Specifically, providers of PGD, including Genesis, did not and could not guarantee favorable outcomes for all cases.

2. The foundation for understanding the process described above involves an introduction to genetics. From Wikipedia, the free encyclopedia, an "Introduction to Genetics," is attached as Pl. Exh. 2.

GENESIS'S REPLY: Rejected to the extent that Plaintiffs rely upon Wikipedia as an authoritative source. That being said, this Court may take judicial notice of basic genetics as taught in high school biology.

3. The following is a glossary of terms required for the factual understanding of the issues in this case:

a. An allele is "one member of a pair [as defined for the purpose of this case taken from Wikipedia] of different forms of a gene." In this case, the mutation for the mother was found at a place described as Exon 11 at G542X. The husband's mutation was located on Exon 10 at DeltaF508.

GENESIS'S REPLY: Not disputed in general terms although Genesis does not accept Wikipedia as a reliable source of information.

b. Heterozygous: "if two alleles are different at one locus, the person is heterozygous at that genetic location." [dna.gov Glossary]

GENESIS'S REPLY: Not disputed in general terms although Genesis does not accept DNA.gov, a site dedicated to "Advancing Criminal Justice Through DNA Technology" as an authoritative source of information concerning medical genetics. Furthermore, Plaintiffs' citation to the glossary on this site is not sufficient to identify the source of their information.

c. Heterozygosity: "the human genome contains two copies of each gene: a paternal and a maternal allele. A mutation affecting only one allele is called heterozygous. When both alleles of a gene harbor mutations, the mutations are difference. The mutations are called compound heterozygous." [Medicinenet.com]

GENESIS'S REPLY: Not disputed in general terms although Genesis does not accept Medicinenet.com as an authoritative source of information related to medical genetics.

d. PCR is a polymerase chain reaction. "The polymerase chain reaction is a scientific technique in molecular biology to amplify a single or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence. Developed in 1983 by Kary Mullis, PCR is now a common and often indispensable technique used in medical and biological research labs for a variety of

applications. These include DNA cloning for sequencing, DNA-based phylogeny, or functional analysis of genes; the diagnosis of hereditary diseases; the identification of genetic fingerprints (used in forensic sciences and paternity testing); and the detection and diagnosis of infections diseases. In 1993, Mullis was awarded the Nobel Prize in Chemistry for his work on PCR." [Wikipedia] Also, a "process used in DNA identification testing in which one or more specific small regions of DNA are copied using a DNA polymerase enzyme so that a sufficient amount of DNA is generated for analysis." [NFSTC' Science Serving Justice]

GENESIS'S REPLY: Not disputed in general terms although Genesis does not accept Wikipedia as an authoritative source of information related to medical genetics. Further, Genesis cannot locate the source Plaintiffs identify as "NFSTC's Science Serving Justice" and therefore cannot comment on the veracity of this information.

e. Allele Dropout: "failure to detect an allele within a sample or failure to amplify an allele during PCR." [dna.gov -, Glossary]

GENESIS'S REPLY: Not disputed in general terms although Genesis does not accept DNA.gov, a site dedicated to "Advancing Criminal Justice Through DNA Technology" as an authoritative source of information concerning medical genetics. Furthermore, Plaintiffs' citation to the glossary on this site is not sufficient to identify the source of their information.

f. Multiplex: a "system for analyzing several loci at once." [dna.gov -a Glossary]

GENESIS'S REPLY: Not disputed in general terms although Genesis does not accept DNA.gov, a site dedicated to "Advancing Criminal Justice Through DNA Technology" as an authoritative source of information concerning medical genetics. Furthermore, Plaintiffs' citation to the glossary on this site is not sufficient to identify the source of their information.

g. Linkage Analysis is another name for multiplex PCR. Linkage is the tendency for genes and other genetic markers to be inherited together because of their location near one another on the same chromosome. Because DNA segments that lie near each other on a chromosome tend to be inherited together, markers are often used as tools for tracking the inheritance pattern of a gene that has not yet been identified, but whose approximate location is known.

GENESIS'S REPLY: Not disputed in general terms although Plaintiffs do not cite to any authority for this contention. Furthermore, Plaintiffs' characterization of markers as "often" being used as tools for tracking inheritance patterns of a gene is rejected as unsupported by citations to competent evidence.

h. Mutation: changes in DNA caused by mutation can cause errors in protein sequence, creating partially or completely non-functional proteins. To function correctly each cell depends on thousands of proteins to function in the right place at the right time. When a mutation alters a protein that plays a critical role in the body, a medical condition can result. A condition caused by mutations in one or more genes is called a genetic disorder. [Wikipedia]

GENESIS'S REPLY: Not disputed in general terms although Genesis does not accept Wikipedia as a reliable source of information.

i. Blastomere: "a type of cell produced by division of the egg after fertilization." [Wikipedia] In this case, the blastomere was the name given to the cell extracted from the embryo during in-vitro fertilization and sent to Genesis Genetics for laboratory analysis as to the presence of the cystic fibrosis gene mutation in the strand of DNA contributed from the mother and the father.

GENESIS'S REPLY: Genesis does not dispute Plaintiffs' definition of blastomere in general terms for purposes of this motion, although Genesis does not accept Wikipedia as a reliable source of information. Plaintiffs' second sentence is rejected as both irrelevant and unsupported by any citation to the record before this Court.

j. Cystic Fibrosis: as noted in the decision in 1981 of Schroeder v. Perkel, 87 N.J. 53 (1981) at Pg. 58:

> Cystic fibrosis is one of the most common fatal genetic diseases in the United States and affects approximately 1 out of every 1,800 babies. An insidious and incurable disease, cystic fibrosis is carried by some parents as a recessive gene.
>
> ***
>
> In general, cystic fibrosis causes certain glands to malfunction and produce abnormally thick mucous. The most commonly affected body systems are the digestive tract and the respiratory system. In the digestive tract, mucous blocks ducts in the pancreas, preventing enzymes from reaching the intestines. One result is an inability to digest fats. Respiratory problems, however, are the most serious symptoms of cystic fibrosis. In the respiratory system, mucous clogs passages and causes air to become trapped in the lungs. Respiratory problems cause chronic pulmonary infection, emphysema and over 90t of all deaths of patients with cystic fibrosis. Metabolic Basis of Inherited Disease 1684 (4th Ed. 1978).

GENESIS'S REPLY: Not disputed for purposes of this motion to the extent that Cystic Fibrosis ("CF") is a genetic disorder that causes the body to produce abnormally thick mucous that commonly causes problems with the digestive track and respiratory system. Rejected to the extent that Plaintiffs rely on a more than thirty year old description of cystic fibrosis as a "fatal" and "insidious" disease.

k. Wrongful Life/Wrongful Birth: the distinction between these two very similar causes of action relates to the ability of the mother to have terminated the pregnancy upon being informed at the appropriate time of the disability of her fetus. See Procanik by Procanik v. Cillo, 97 N.J. 339, 347-348 {1984).

GENESIS'S REPLY: Rejected. Courts have consistently defined "wrongful birth" claims as claims by parents who have given birth to children who, they claim, would not have been born but for a defendant's alleged medical malpractice; "wrongful life" claims, on the other hand, are claims by individuals (usually children through

their parents) who claim that they themselves would not have been born but for a defendant's alleged medical malpractice. See Genesis's Mot. Summ. J. at 12-13 (citing to *Berman v. Allen*, 80 N.J. 421 (1979) and *Procanik v. Cillo*, 97 N.J. 339 (1984)). Therefore, Chaya and Menachem Grossbaum's claims are wrongful birth claims; Rosie Grossbaum's claim is a wrongful life claim.

4. Plaintiffs chose to undertake IVF and PGD to reduce their 25 percent chance of having an affected child. (Declaration of Chaya Grossbaum; P1. Exh. 3.)

GENESIS'S REPLY: Not disputed.

5. The medical community recognized that "Couples whose children are at increased risk for a specific genetic disorder can benefit from PGD.... PGD is an alternative to prenatal tests such as amniocentesis or chorionic villas sampling and since it is performed before a pregnancy has begun, it may be more acceptable to couples who ... have objections to termination of pregnancy." (See "Review: Molecular Diagnostics in Preimplantation Genetic Diagnosis" out of the Mayo Clinic, Department of Laboratory Medicine and Pathology, published in Journal of Molecular Diagnostics, No. 4, No. 1, February 2002 at Page 11; learned treatise produced by the Plaintiffs to the Defendants in discovery; P1. Exh. 4.)

GENESIS'S REPLY: Accepted that Plaintiffs produced the cited article containing the referenced quotation during discovery; rejected to the extent that Plaintiffs contend that "the medical community recognized" the concept set forth in the quotation. Genesis does not know who Plaintiffs are referring to as "the medical community."

6. PGD was well recognized in Europe in the publications of the European Society of Human Reproduction and Embryology. The doctors at the Department of Molecular Cell Biology and Genetics, and the Department of Obstetrics and Gynecology at Academic Hospital, Maastricht, The Netherlands, published first at the Annual Meeting of the European Society of Human Reproduction and Embryology in June 1999 at Tours, France, and later in the journal, Molecular Human Reproduction, Vol. 6, No. 5, Pages 391-396, in the year 2000, that "for couples at risk of transferring a genetic disorder to their offspring,

PGD offers an alternative to prenatal diagnosis. By choosing PGD, the difficult decision of pregnancy termination after genetic diagnosis by chorionic villus sampling or amniocentesis in the first and second trimesters of gestation can be avoided." (Pl. Exh. 5 at Page 391.)

GENESIS'S REPLY: Genesis does not dispute that the cited articles contained the referenced quotations. Genesis rejects this contention as unsupported with citations to competent evidence and irrelevant to the U.S. standard of care to the extent that Plaintiffs' contend that "PGD was well recognized in Europe in the publications of the European Society of Human Reproduction and Embryology."

7. As stated in the Declaration of Chaya Grossbaum at Pl. Exh. 3:

a. I have been a New Jersey resident all of my life with the exception of three years after my marriage in August, 2002 when my husband and I temporarily lived in Brooklyn, New York prior to our childbearing years. It was always our intention to move back to New Jersey when we began a family.

b. I was born in Morristown, New Jersey and went to the Morristown schools, except for the last two years of high school, when I went away to school. I met my husband when I was in high school in Morristown, New Jersey, and he was a student at the Rabbinical College of America, also in Morristown, New Jersey,

c. My parents have been New Jersey residents since before I was born. My husband was born and raised in Minnesota.

d. Our family plan was that when I had our first baby we would return to New Jersey. In pursuit of that plan: (a) I came under the care of Marla Scott, CNM and Judy Caruso, CNM at Midwives of Denville, Boonton, NJ; (b) delivered the baby, Rosie, at Saint Clare's Hospital-Denville Campus, Denville, New Jersey; (c) prior to the baby's birth, arranged for a pediatrician, Dr. Richard Dicker, whose practice was located at 10 Broadway in Denville, New Jersey.

e. In addition, when I was informed, two weeks after Rosie was born, that she was a cystic fibrosis baby, I arranged for consultation with the Cystic Fibrosis Center at Morristown Memorial Hospital, Morristown, New Jersey, where Rosie has been a patient since her birth approximately six years ago.

f. The only reason for having contact with NYU Medical Center and its Fertility Clinic was the IVF services offered by that institution allowed a rabbi to oversee the IVF processes to confirm compliance with Jewish law.

GENESIS'S REPLY: Not disputed.

8. When the Plaintiffs began the process of IVF/PGD, it was known that they were both carriers of the cystic fibrosis gene mutation, which was characterized as compound heterozygous. (Genesis Exh. 13 at CG018, CG019, CG021.)

GENESIS'S REPLY: Not disputed.

9. The significance of compound heterozygous mutations was well described in the medical literature, and particularly in the aforementioned Mayo Clinic article by Dr. Alan R. Thornhill, the paper stated:

> ...for compound heterozygous...conditions, the consequences of ADO [allele dropout] can be catastrophic, as misdiagnosis and subsequent transfer of affected embryos can occur. Indeed ADO is the most likely cause of reported errors in PGD of cystic fibrosis in which affected compound heterozygote embryos were misdiagnosed as carrier embryos because the analysis used could only detect one of the inherited mutations. (P1. Exh. 4 at Page 14.)

GENESIS'S REPLY: Genesis does not dispute that the cited article contains the referenced quotation and speaks for itself. Genesis rejects this statement as unsupported and without citation to the record or other

competent evidence to the extent that it purports to characterize the "significance of compound heterozygous mutations" as "well described in the medical literature" or particularly well described in the cited article.

10. Also from the aforementioned publication:

In addition to reducing ADO, strategies have been proposed to increase the detection of ADO. One such strategy is the use of linked markers which simultaneously controls for contamination. Use of one or two liked markers reduces undetected ADO by approximately 50% and 75% respectively and with three linked markers ADO is virtually always detected. The use of linked markers carries considerable advantages not only from the point of view of reducing the possibility of misdiagnosis, but also by potentially increasing the number of embryos available for transfer.

GENESIS'S REPLY: Genesis does not dispute that the cited article contains the referenced quotation and speaks for itself.

11. Genesis Genetics and Dr. Hughes did not use linkage analysis in analyzing the cells from embryos sent by NYU on behalf of the Plaintiffs. Notwithstanding what Dr. Hughes said in his declaration submitted as Exhibit 6 by the Defendants Genesis Genetics and Hughes, in his first deposition on February 19, 2009, Dr. Hughes admitted that Genesis Genetics had the technology to perform linkage analysis, but did not do so. Dr. Hughes was specifically asked in his deposition:

Q. Were you aware that that type of testing was done at other laboratories in the United States?

A. We were all trying to do it, which was why I wanted to have those embryos, so we can set genetic phase for the family, and do that. ...in order to look at polymorphic markers you need to have some way to link the marker to the mutation. ...we had the equipment to do it, but we needed to have another sample, so you need a member of the family. If this couple had a healthy child or if this couple had an affected child or a sister or a brother

> that were carriers that we could get a sample from, the idea would be then, to look at those markers and set what's called "genetic phase" to determine whether the marker - which markers are linked to the mutation.

(Hughes Dep. 2/19/09 T:57-8 to 57-25; Pl. Exh. 6.)

> **GENESIS'S REPLY:** Rejected. Dr. Hughes explained that in 2004, Genesis did not yet have the technology to provide multiplex testing PCR such that it was producing results as good or better than those achieved by Genesis using without using multiplex testing. As Dr. Hughes testified: "And this was all coming out. But we had a 1.2 percent error rate, which was significantly less than anybody else was reporting, so – and we were having difficulties getting multiplex PCR to make that better or look like it make it better [sic]. Theoretically we could see where it was quite valuable, but we were not happy with the results, in those early papers we weren't able to produce them." (Blaine Decl. Ex. 2 at 47:24 – 48:6.) Therefore, in direct contravention of Plaintiffs' assertions, Dr. Hughes testified that when they provided PGD to the Grossbaums, Genesis had not yet been able to develop multiplex testing sufficiently to make it commercially viable.

12. After stating that he needed more information about the Grossbaums, he stated:

> If they had to go through this another time, we would then try to develop a better test using those genomic markers.

(Hughes Dep. 2/19/09 T:58-12 to 58-14; Pl. Exh. 6.)

> **GENESIS'S REPLY:** Rejected. See Genesis's Reply to Pls.' Supplemental Resp., ¶ 11. The testimony speaks for itself.

13. Dr. Hughes also admitted that he was "perfectly aware of all of that technology." (Hughes Dep. 2/19/09 T:58-21 to 58-22; Pl. Exh. 6.)

> **GENESIS'S REPLY:** Rejected. See Genesis's Reply to Pls.' Supplemental Resp., ¶ 11. The testimony speaks for itself.

14. Dr. Hughes agreed that "if the cause of the misdiagnosis was allele dropout, if that was the cause of the problem, and if we had a. sample that they would give us that would allow us to use the technology, absolutely, it would have helped, and we do that routinely now." (Hughes Dep. 2/19/09 T:59-21 to 59-25; P1. Exh. 6.)

GENESIS'S REPLY: Rejected. See Genesis's Reply to Pls.' Supplemental Resp., ¶ 11. The testimony speaks for itself.

15. Dr. Hughes further claimed that he asked for the required samples of the Grossbaums in order to do linkage analysis, but claimed "they didn't want to give them to us, but I can't be sure." (Hughes Dep. 2/19/09 T:60-22 to 60-23; Pl. Exh. 6.)

GENESIS'S REPLY: Rejected. See Genesis's Reply to Pls.' Supplemental Resp., ¶ 11. The testimony speaks for itself.

16. Plaintiff, Chaya Grossbaum, declared that neither Dr. Hughes nor anyone else asked them to supply blood samples from other members of the family which would have satisfied Dr. Hughes' need to do the linkage analysis. (Declaration of Chaya Grossbaum; Pl. Exh. 3.)

GENESIS'S REPLY: Rejected. See Blaine Decl. Ex. 7 at 3, in which Dr. Hughes's notes state "? Blood possible from parents? Seems not." See also Genesis's Reply to Pls.' Supplemental Resp., ¶ 11.

17. Dr. Charles R. Strom, Plaintiffs' consultant expert on laboratory tests for cystic fibrosis in PGD, and the author of such papers as "Genetics: Reliability of Polymerase Chain Reaction (PCR) Analysis of Single Cells for Preimplantation Genetic Diagnosis," published in the Journal of Assisted Reproduction and Genetics, Vol. 11 No. 2, 1994 [emphasis supplied], stated at depositions:

> ...The concept of multiplex PCR for the detection of allele dropout was well established by the year 2000 when [he] left RGI [Reproduction Genetic Institute of Chicago]. Other people began instituting them in their own programs at that point and the Thornhill report was what he had implemented.

(Strom Dep. 5/4/10 T:38-22 to 39-5; Pl. Exh. 7.)

> **GENESIS'S REPLY:** Genesis does not dispute that Dr. Charles R. Strom has been offered by Plaintiffs as their consultant expert on laboratory tests for cystic fibrosis in PGD, that he is the author of the referenced papers, and that he made the quoted statement at his May 4, 2010 deposition.

18. The laboratory records of the analysis of the Plaintiffs' embryos on the page labeled "DNA Sequencing – Genotyping Assay" in the handwriting of Dr. Mark Hughes came the statement, "always concerned for ADO (we should try to obtain untransfered embryos for next time assay)." This latter comment allows for only one factual conclusion: there was an issue as to the suitability as to the embryos for implantation from the DNA studies by Genesis Genetics; there was the potential for needing another group of embryos at a later time; there were techniques to improve the reliability of the studies in the next submission of embryos from the Plaintiffs by using "linkage analysis." (Pl. Exh. 8.)

> **GENESIS'S REPLY:** The quoted document speaks for itself. Plaintiffs' assertion that this is Dr. Mark Hughes's handwriting is unsupported, and it is argumentative rather than stating facts, much less undisputed facts. Plaintiffs' characterization of this comment is not supported by the record, and certain does not allow "for only one factual conclusion." Plaintiffs' baseless inferences from this comment should be rejected by this Court, especially in light of the testimony of Dr. Hughes, cited at ¶ 11 above, that Genesis was not yet prepared to offer multiplex testing for commercial use. Regardless, Plaintiffs' assertions are not relevant to this Court's determination of the issues before it on Genesis's summary judgment motion.

19. The Genesis Genetics records contained a page labeled "Message" (Pl. Exh. 9) addressed to "NYU IVF Team" that contained the statement, "We are

disappointed with the results given the large number of amplification failures for one of the two CFTR alleles...If the couple chooses a transfer with this partial data set, those samples displaying the G allele at G542X would be predicted unaffected, assuming no allele dropout. However, ADO is possible in compound heterozygote testing such as this, and even more likely given the embryo quality." The memo went on to emphasize the need for prenatal testing and contemplated the potential for the Plaintiffs rejecting further IVF procedures because of the poor quality of the laboratory studies up until then.

GENESIS'S REPLY: The referenced document speaks for itself. Plaintiffs' characterization of the memo as "emphasizing" the "need" for prenatal testing is not supported by the document. Similarly, Plaintiffs' characterization of the memo as "contemplat[ing] the potential for the Plaintiffs rejecting further IVF procedures because of the poor quality of the laboratory studies up until then" is not supported by the referenced document.

20. In Genesis Genetics Institute's final report (P1. Exh. 10) at Page 2: there is a clear indication that the outcome of the analysis was "disappointing." The gene location for the mutation on the chromosome was studied under testing that "has been routinely performed since 1991." The reasons for the "disappointing" outcome were elaborated upon. Allele dropout was emphasized as "a distinct concern in this sample set." The concern for allele dropout "could result in a misdiagnosis." The laboratory was relying on the informed consent of the Plaintiffs to exonerate any responsibility it would have for implantation of a "disappointing" study. Dr. Hughes further advised NYU of the statistical risk of misdiagnosis in the general population—a further indication that the studies could present a real danger of a misdiagnosis.

GENESIS'S REPLY: The referenced document speaks for itself. Plaintiffs' characterizations of the document should be rejected in favor of the text of the document itself especially Plaintiffs' assertion that this document supports the proposition that "[t]he laboratory was relying on the informed consent of the Plaintiffs to exonerate any responsibility it would have for implantation of a 'disappointing' study." Similarly, Plaintiffs' conclusion that "Dr. Hughes further advised NYU of the statistical risk of misdiagnosis in the general population—a further indication that the studies could present a real danger of misdiagnosis" is unsupported by the referenced document or the record generally.

21. Dr. Hughes in his expert deposition of May 14, 2010 claimed that the documents referred to in No. 19 and No. 20 above (P1. Exh. 9 and Pl. Exh. 10) were his actual final report to NYU. (Hughes Dep. 5/14/10 T: 66-3 to 66-7; Pl. Exh. 1I.)

Comment: notwithstanding that the documents referred to in P1. Exh. 9 and Pl. Exh. 10 were part of the Genesis Genetics records of their studies in this case, and are not disputed by Genesis Genetics, they were omitted from the Defendant, Genesis Genetics' submission to this Court under the guise, as stated in the footnote at Page 6 of Genesis Genetics' Statement of Undisputed Material Facts, that they were the subject of "hot factual dispute."

GENESIS'S REPLY: The record and referenced documents speak for themselves. Plaintiffs' contention that Genesis's intent in excluding these documents from the affirmative summary judgment record was nefarious is belied by the record. Genesis referenced these documents and noted that they are the subject of a fact dispute that is not relevant to the determination of the summary judgment motion. Specifically, that dispute is between Genesis and NYU, and concerns the fact that these documents, which Genesis sent to NYU, were not found in the medical records maintained by NYU for Chaya Grossbaum. That dispute, however, as well as the records themselves, is irrelevant to the Court's determination of the choice of law, statute of limitations, and causation issues that form the heart of Genesis's summary judgment motion.

22. Plaintiffs, Chaya Grossbaum and her husband, assert that they were never advised by Genesis Genetics and Dr. Hughes or Dr. Licciardi, or anyone else at NYU, that the studies were sub-optimal, that they were disappointing, that risk of ADO was a significant consideration, and that ADO could be responsible for a misdiagnosis and the birth of an affected child if they went ahead with the IVF procedure. (Declaration of Chaya Grossbaum; Pl. Exh. 3.)

GENESIS'S REPLY: Genesis does not dispute that Plaintiffs assert that they were never advised of these facts. Those alleged facts are irrelevant to this Court's determination of Genesis's summary judgment motion, which is based largely on choice of law, statute of limitations, and causation issues.

23. Attached as Exh. 12 is the curriculum vitae of Charles Strom, M.D., Ph.D., FAAP, FACMG, H.C.L.D., Medical Director, Genetic Testing Center Quest Diagnostics, Nicholas Institute (and former Medical Director and Director of the DNA Laboratory at Reproductive Institute in Chicago from May 1988 to October 2000), Plaintiffs' expert.

GENESIS'S REPLY: Not disputed.

24. Genesis Genetics and Dr. Hughes provided laboratory services to New York and NYU on approximately 50 occasions. (Hughes Dep. 2/19/09 T:17-13; P1. Exh. 6.) Genesis Genetics' website lists on a page entitled "Our Partners four fertility clinics in New Jersey including Cooper IVF, New Jersey IVF, RMA New Jersey and South Jersey Fertility. (See copy of website page annexed hereto as Pl. Exh. 13.) In addition, in the Interrogatory Answers at Pages 2 and 3, Genesis Genetics and Dr. Hughes indicated that they were being sued in connection with their laboratory work in the States of California and Tennessee. (Pl. Exh. 14.) Likewise, the resume of his qualifications provided in conjunction with Dr. Hughes' report of March 2, 2010 contains the statement: "Genesis Genetics Institute, where the diagnostic aspects of PGD are provided to over 270 human reproductive centers in North and South America, Europe and now Asia." (Pl. Exh. 15.) Dr. Samuel Pang, Medical Director of the Reproductive Science Center, Lexington, Massachusetts, indicated that "we work with Dr. Hughes for PGD." (Pang Dep. 11/23/10 T:9-18; P1. Exh. 16.) As far back as July 16, 2004 (the same time that the Grossbaums' studies were being performed), Dr. Hughes was giving a lecture, the abstract of which included his bio in which it was indicated that "last year he formed the Genesis Genetics Institute which performs human embryo testing for couples worldwide." (P1. Exh. 17.)

GENESIS'S REPLY: Not disputed.

25. According to Dr. Hughes, the purpose of soliciting and obtaining the Plaintiffs' agreement to have prenatal testing (CVS or amniocentesis) was not "to facilitate aborting a CF baby," but "to find out the integrity of the single cell testing that we are doing on this project. As a scientist, we have to be monitoring this. If we didn't, it would not be scientific and it certainly would be unethical." Also, Hughes stated, "...we want to monitor the quality of our data, knowing that it

isn't perfect. We need to monitor it frequently, and the most frequently we can do it is at a CVS or amniocentesis stage, so that's when we require the testing to be done." And further, "From my personal perspective [Hughes] of this project, that's the only reason...." (Hughes Dep. 2/19/09 T:34-25 to T:37-20; Pl. Exh. 6 in which information was obtained notwithstanding the obstructionism of defense counsel.)

GENESIS'S REPLY: The testimony speaks for itself. Plaintiffs' editorializing is rejected as unsupported by the record.

Respectfully submitted,

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DATED: March 10, 2011